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- See application file for complete search history.

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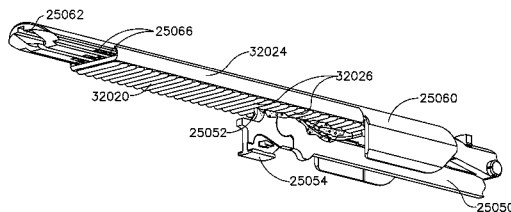
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(57) **ABSTRACT**

In various embodiments, a compensator can comprise a compensator body comprising a plurality of first packets and a plurality of second packets wherein, in at least one embodiment, each second packet is positioned intermediate two or more first packets. The compensator can further comprise a first medicament positioned within each first packet and a second medicament positioned within each second packet, wherein the first medicament is different than the second medicament.

**20 Claims, 147 Drawing Sheets**



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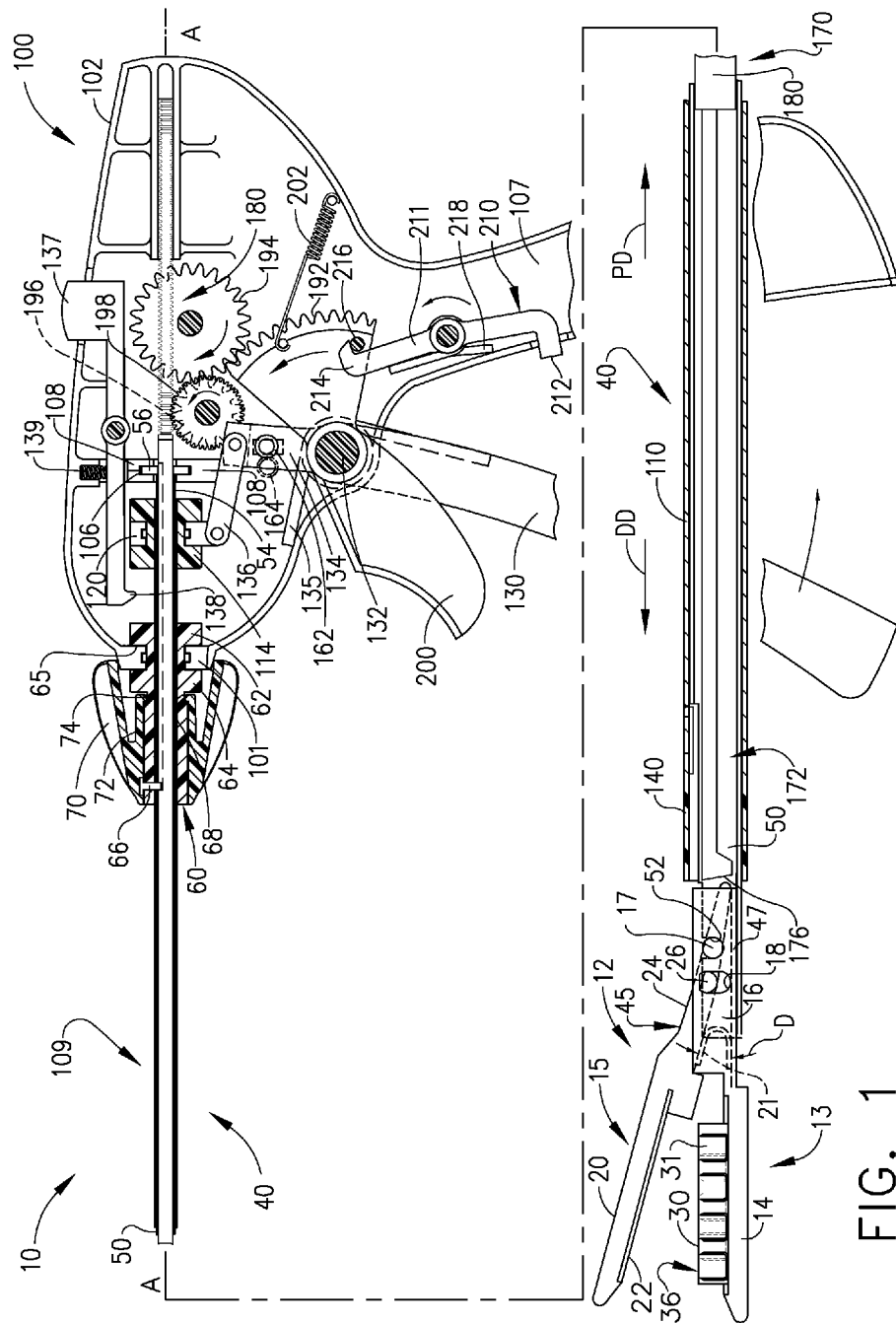
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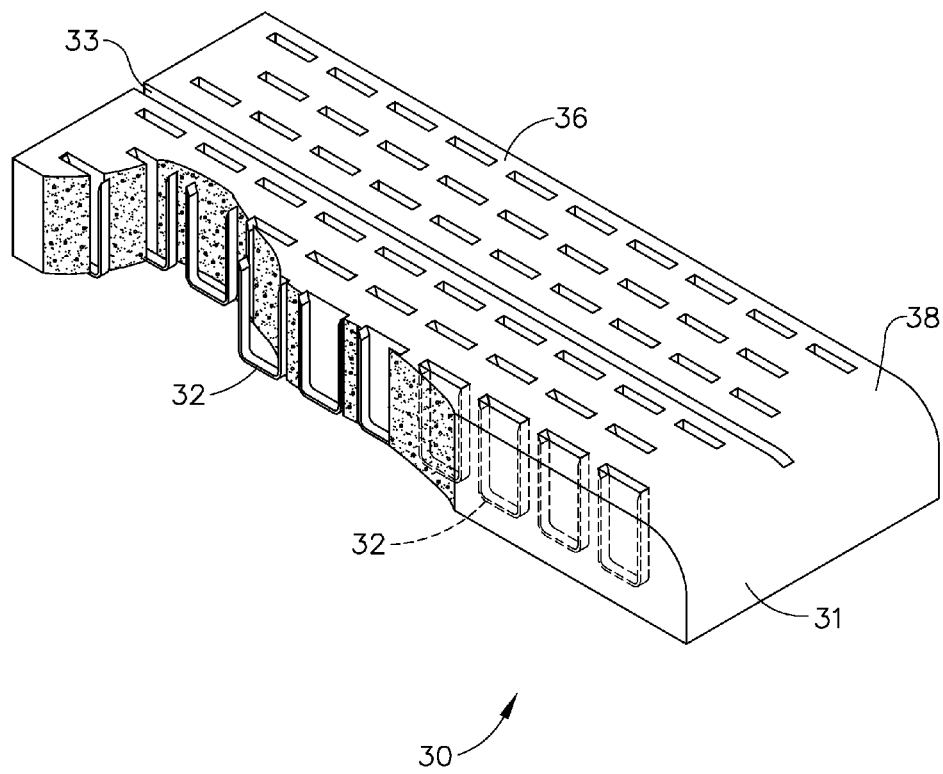


FIG. 1A



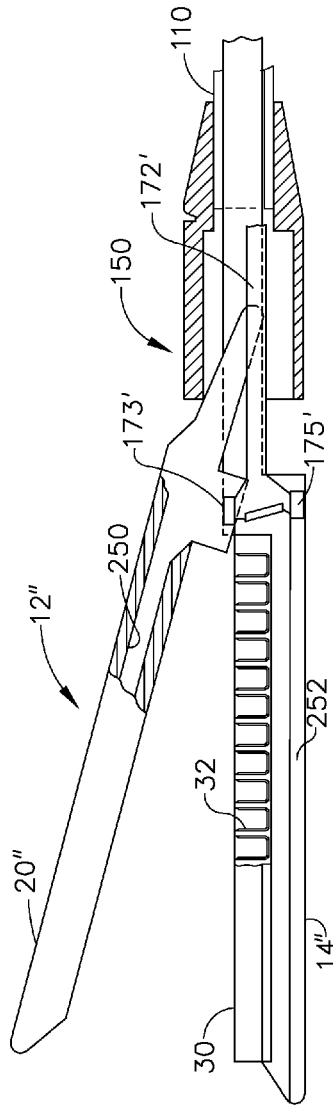


FIG. 2

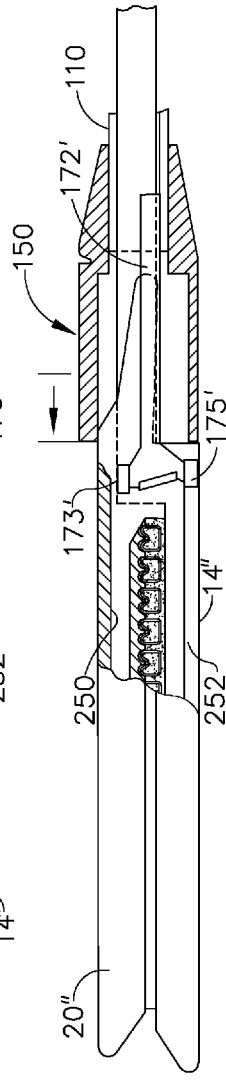


FIG. 3

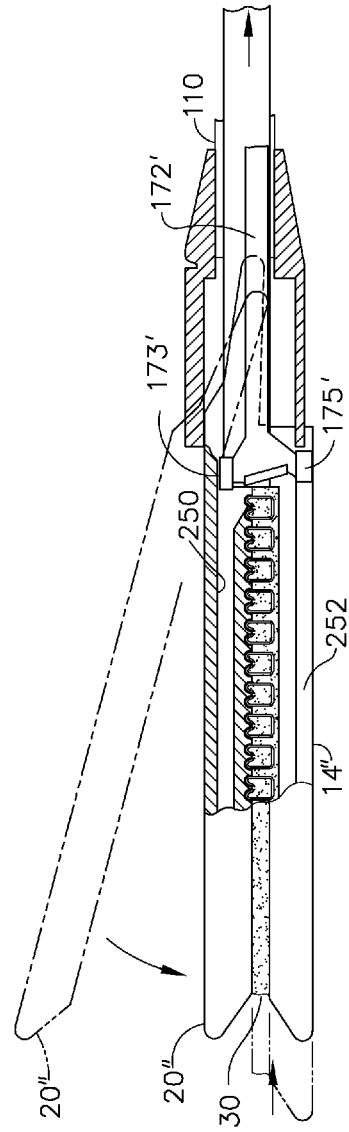


FIG. 4

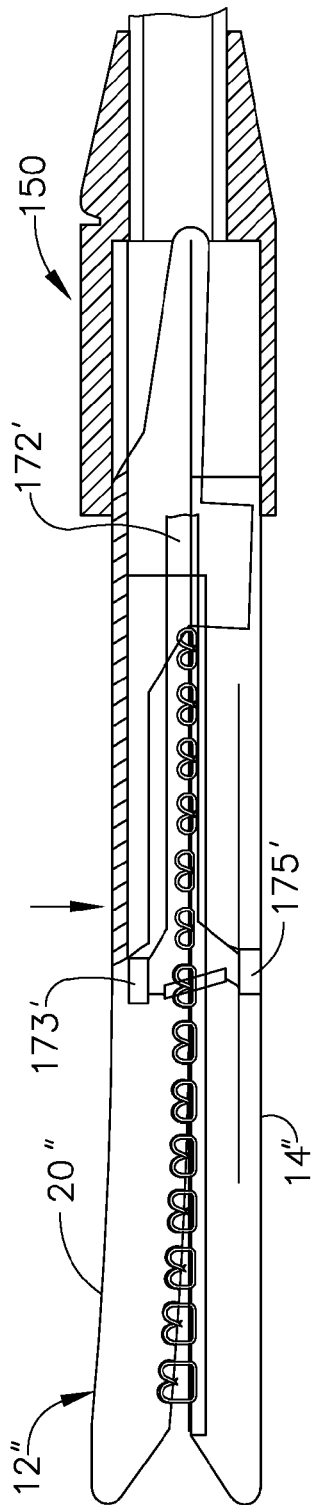
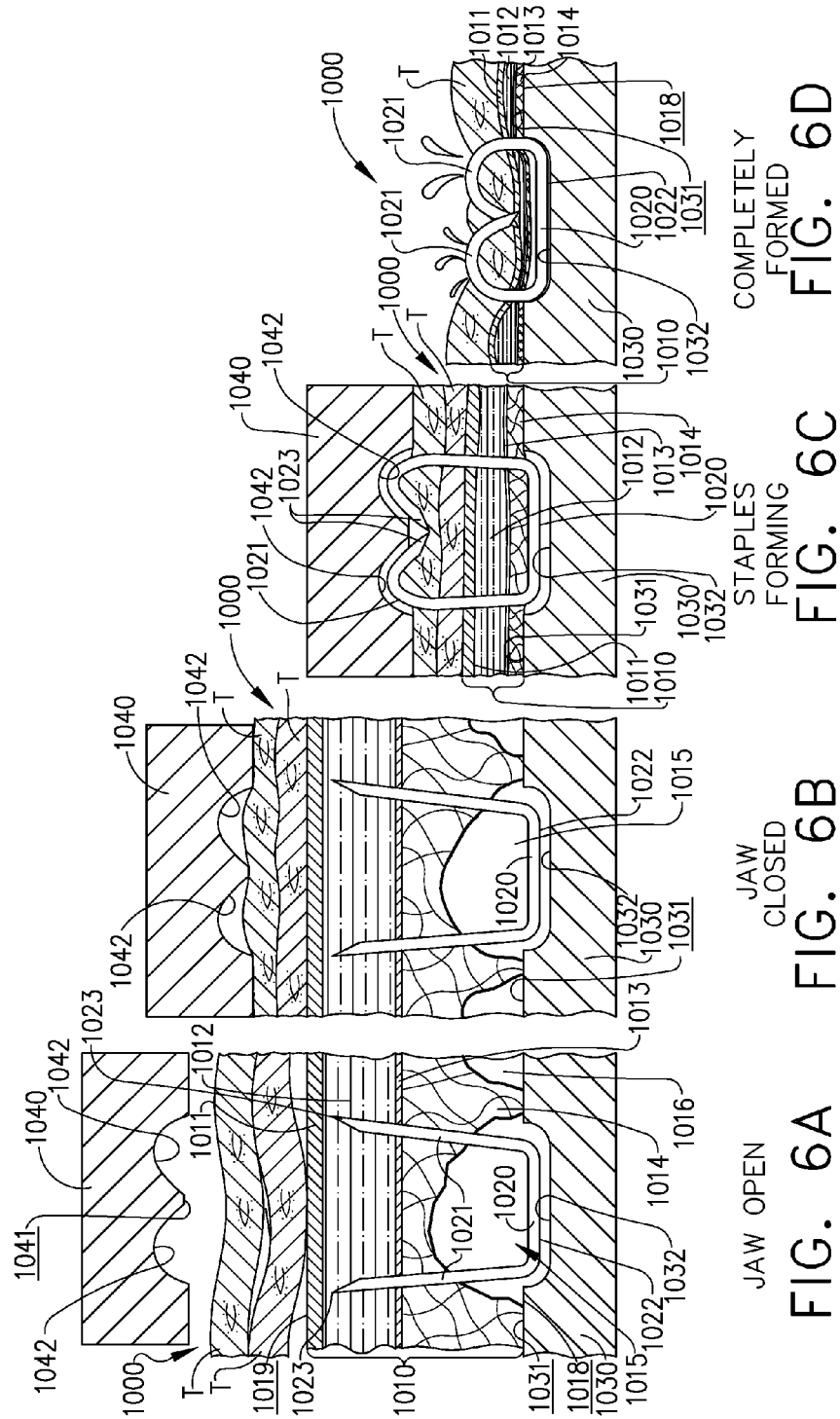


FIG. 5



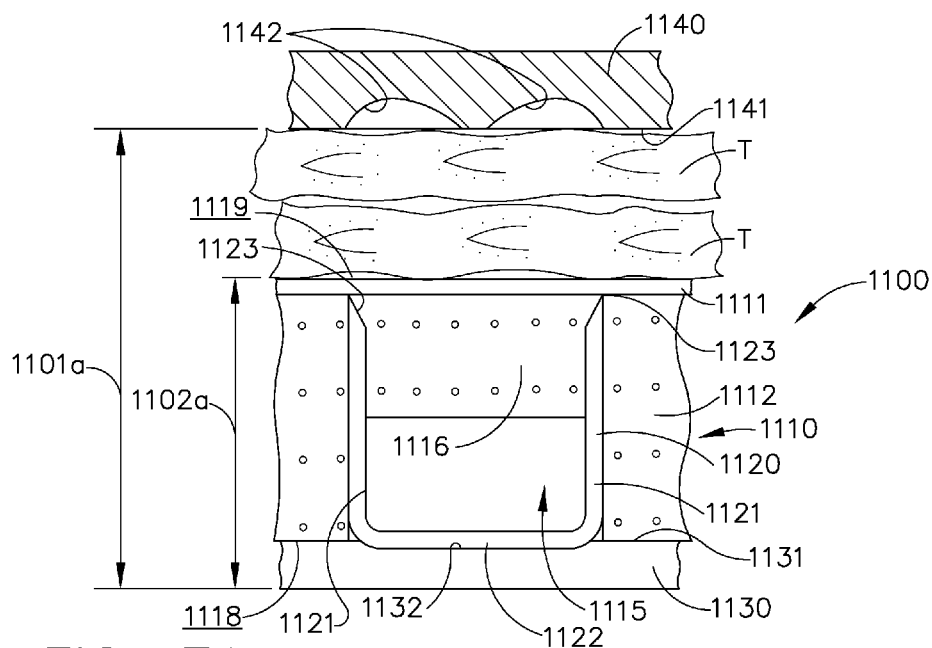


FIG. 7A

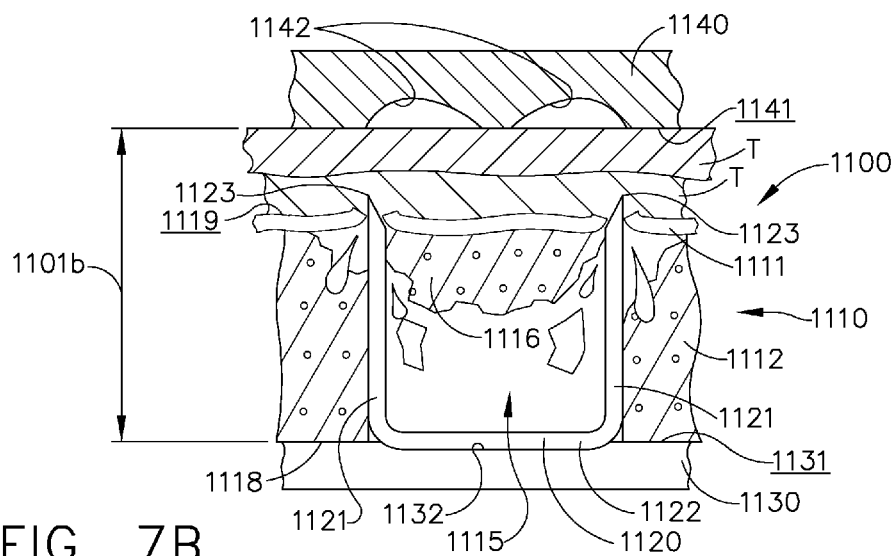


FIG. 7B

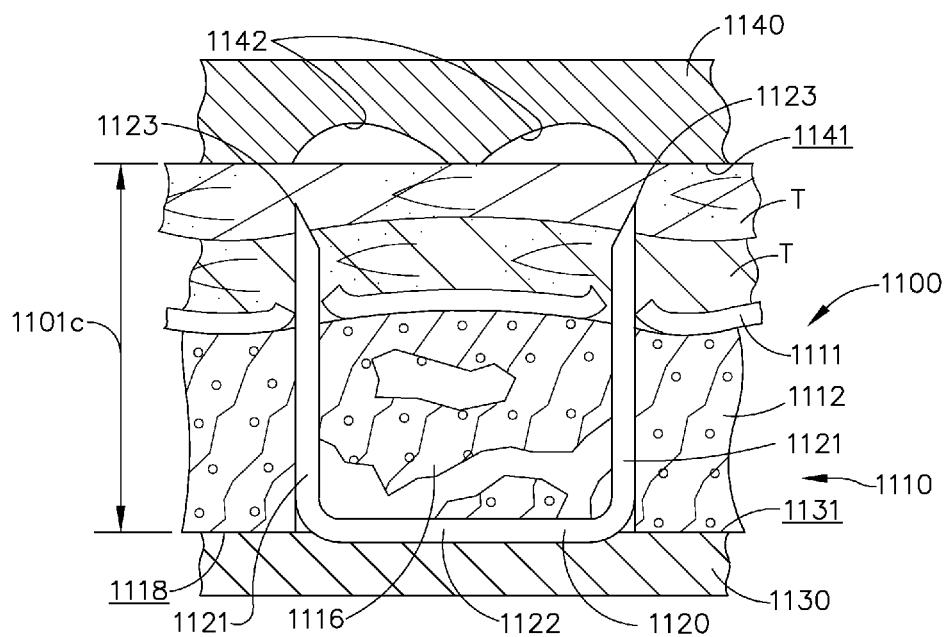


FIG. 7C

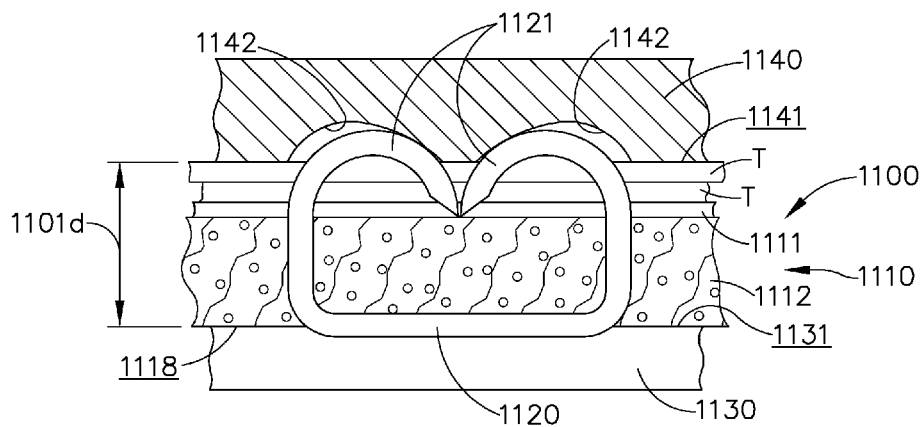


FIG. 7D



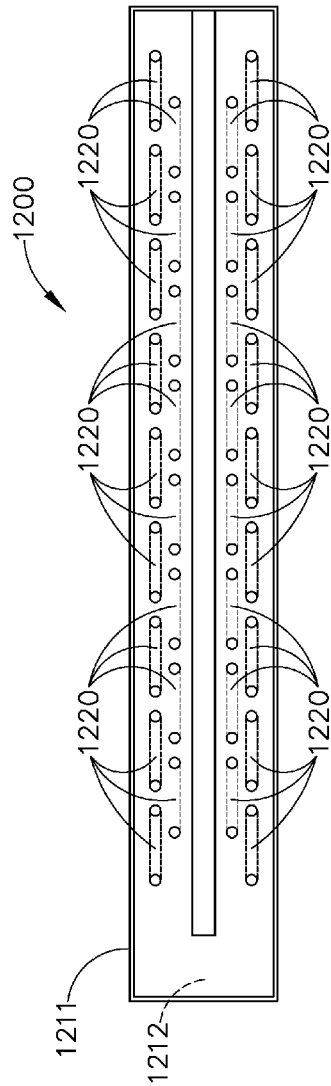


FIG. 8

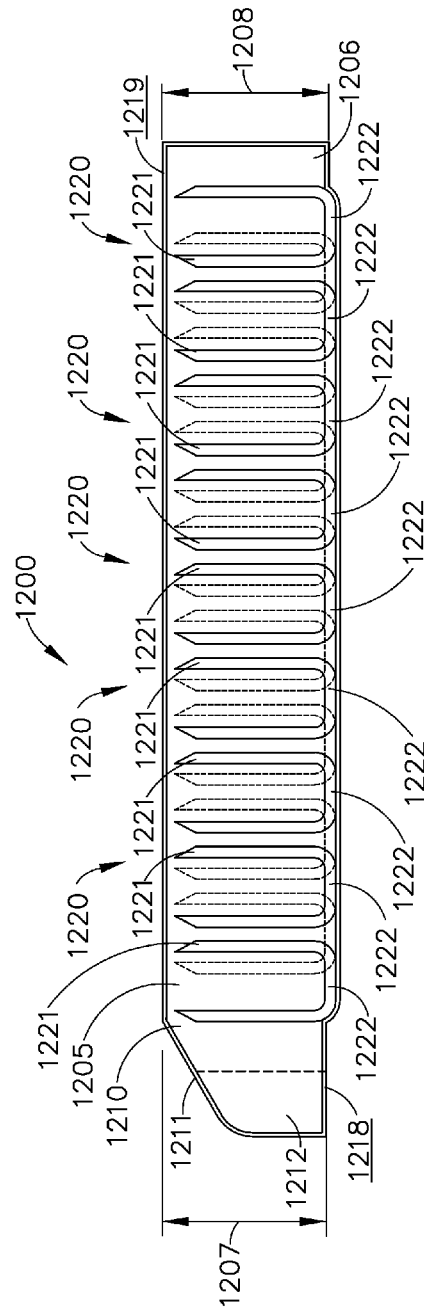


FIG. 9

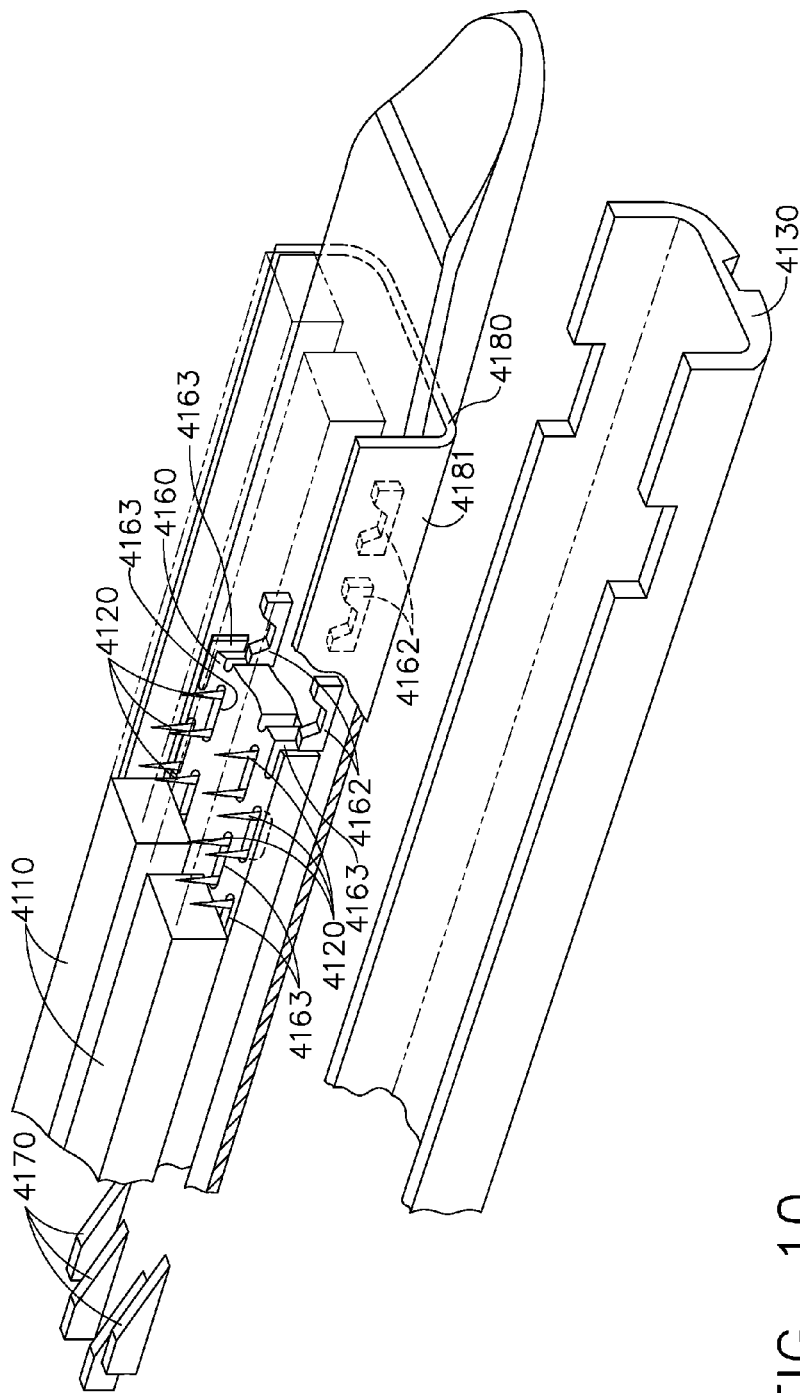


FIG. 10

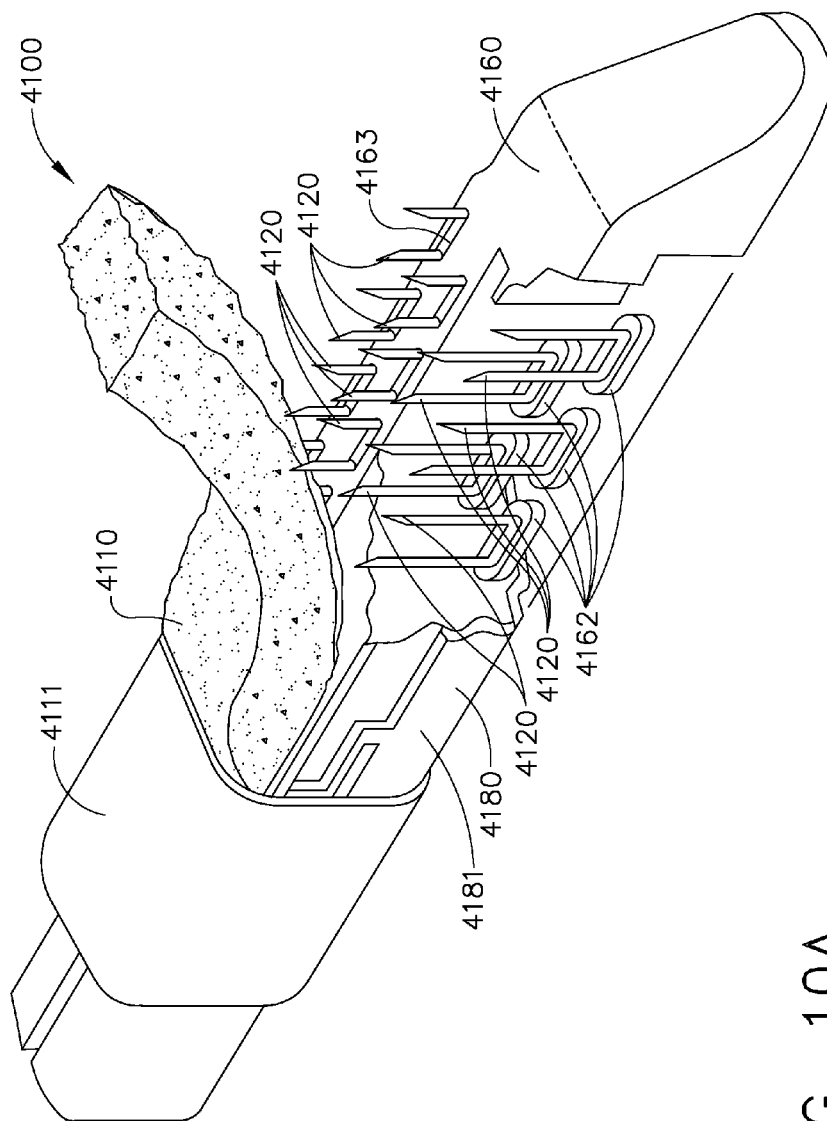


FIG. 10A

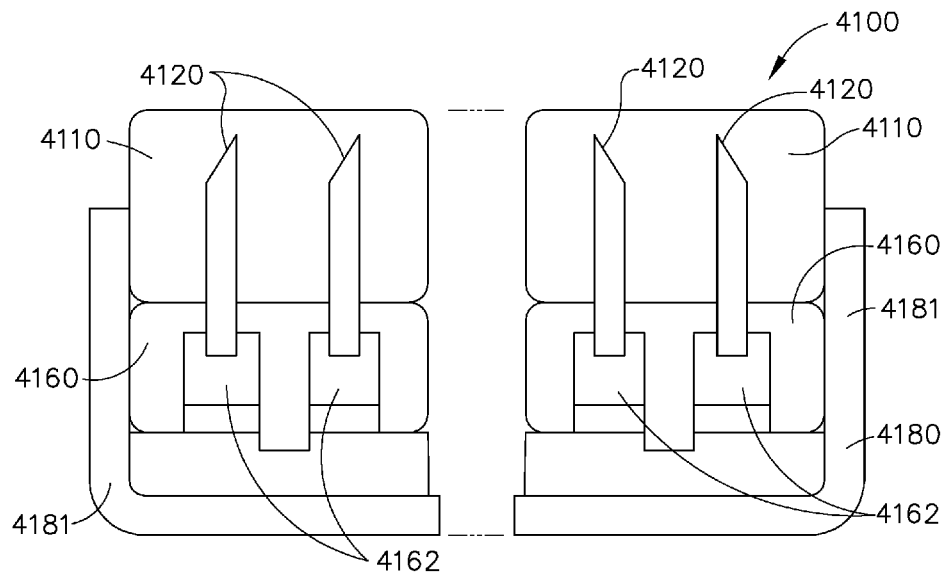


FIG. 11

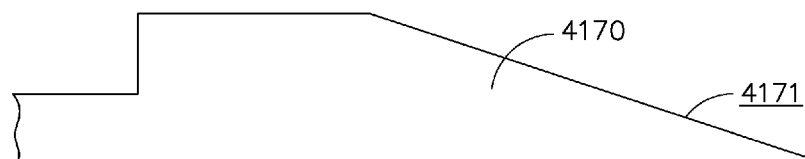


FIG. 12

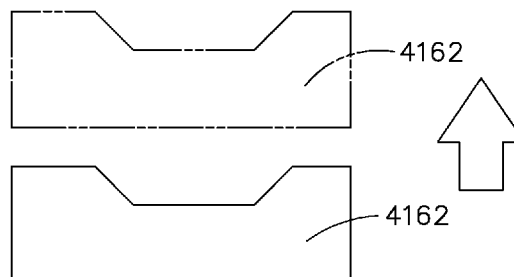


FIG. 13

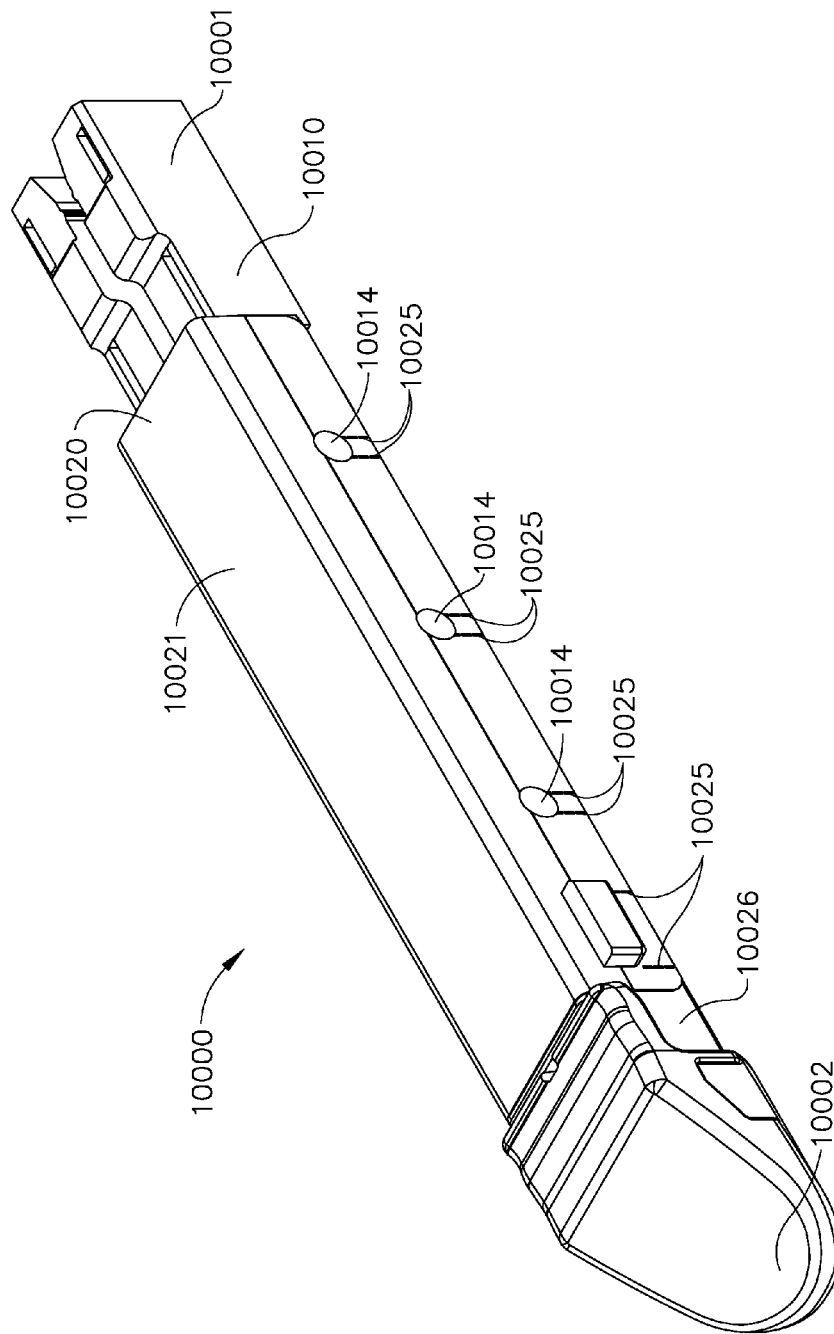


FIG. 14

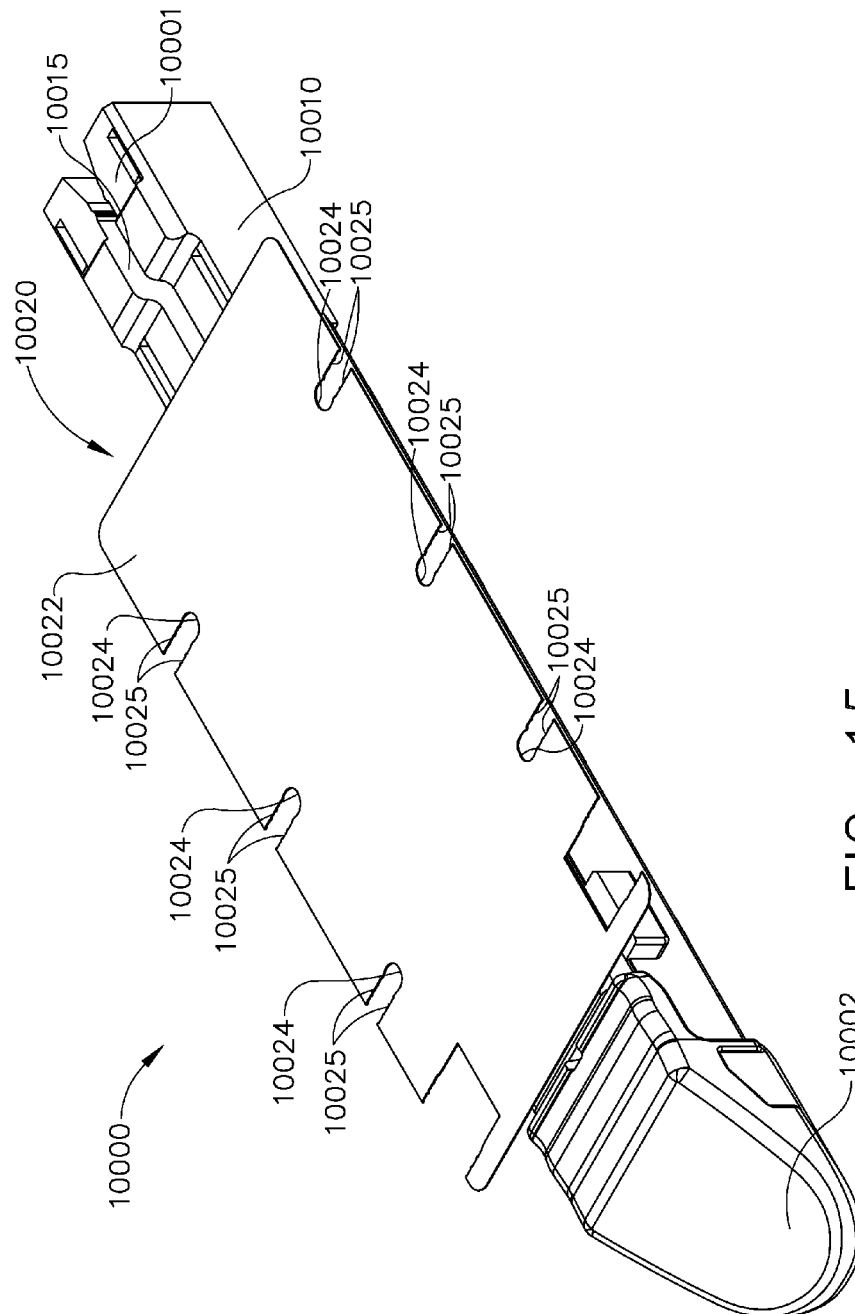


FIG. 15

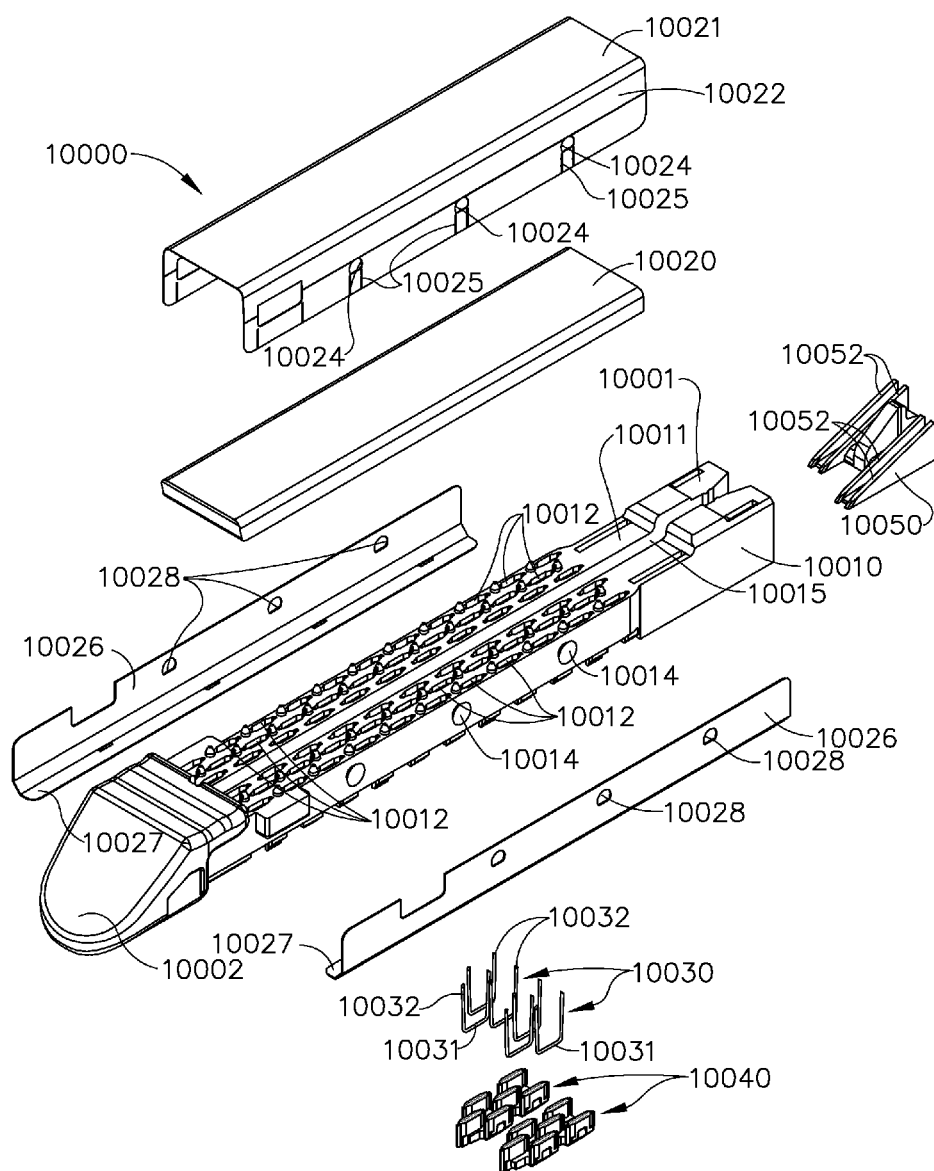


FIG. 16

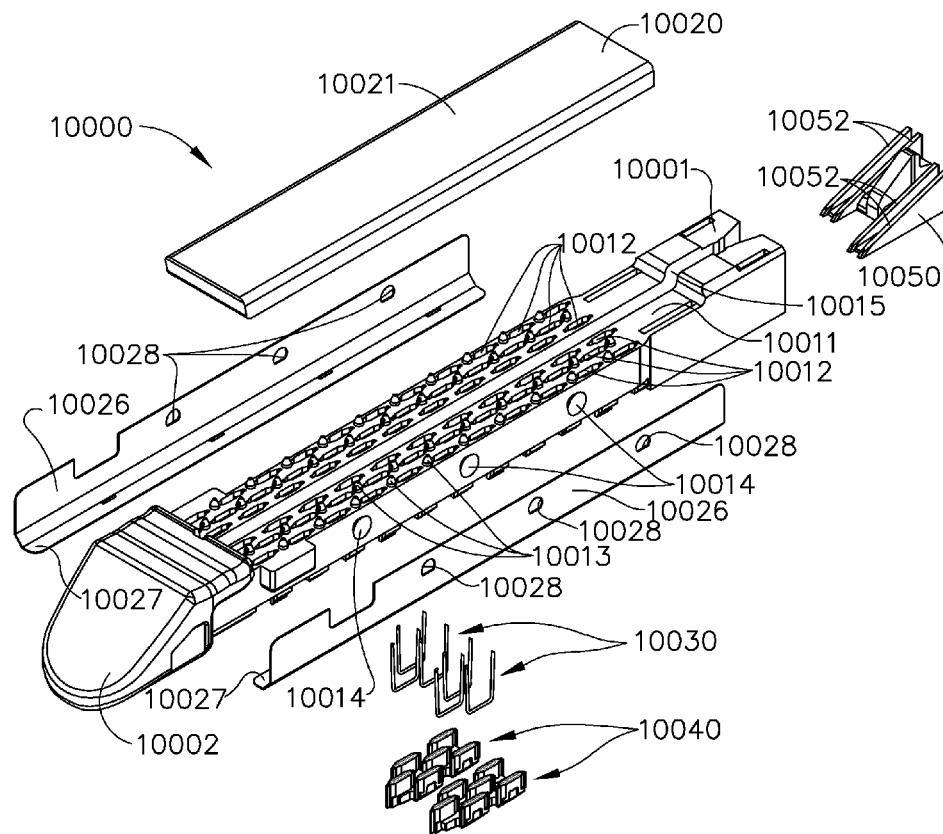


FIG. 17



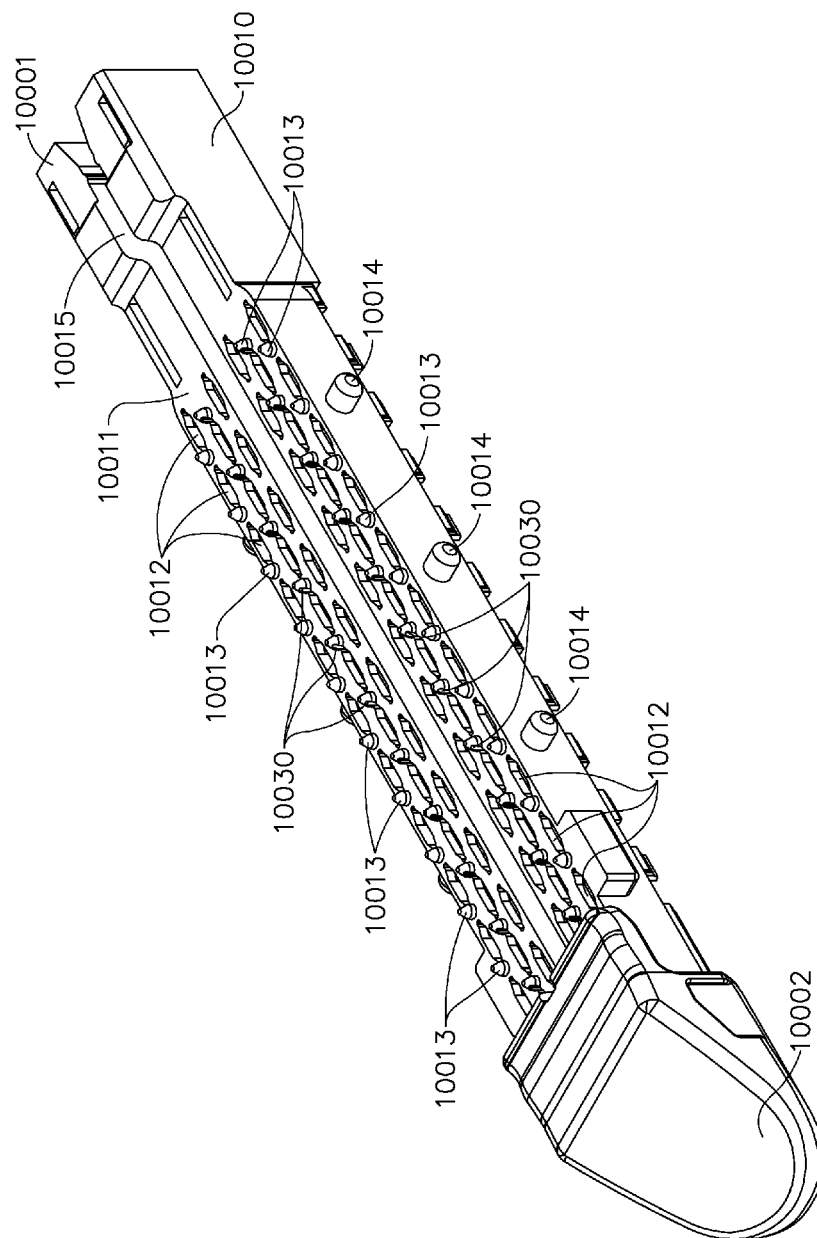


FIG. 18

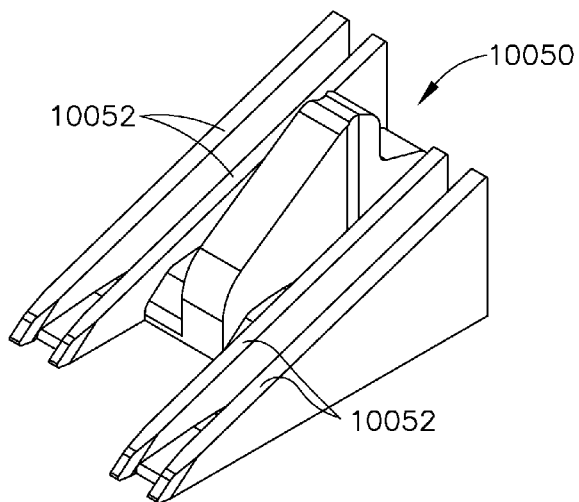


FIG. 19

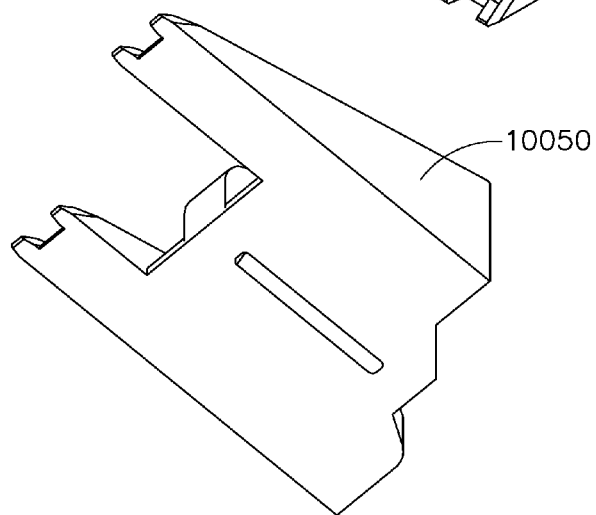


FIG. 20

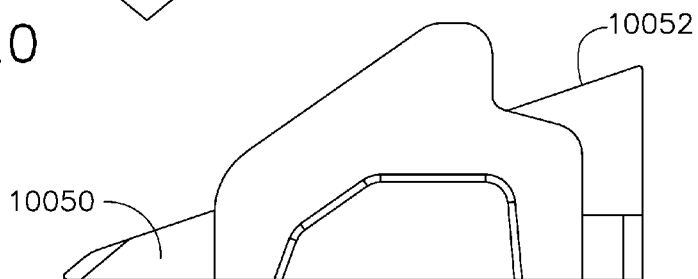


FIG. 21

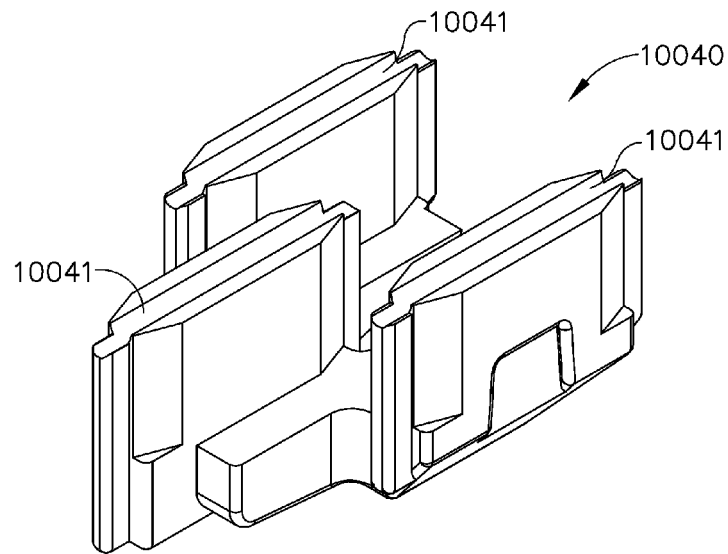


FIG. 22

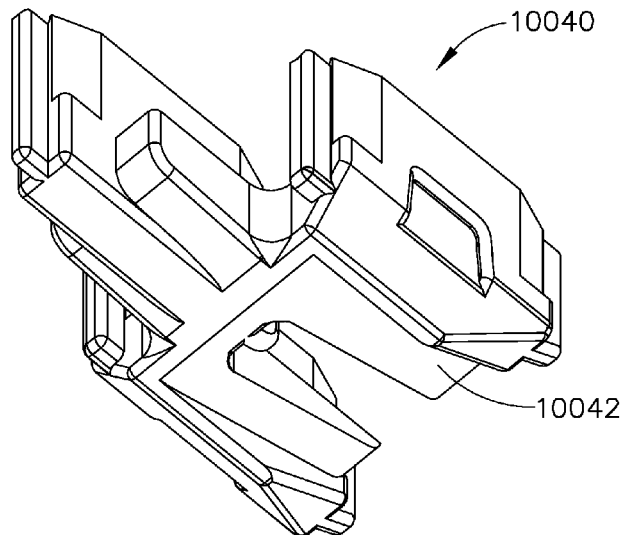
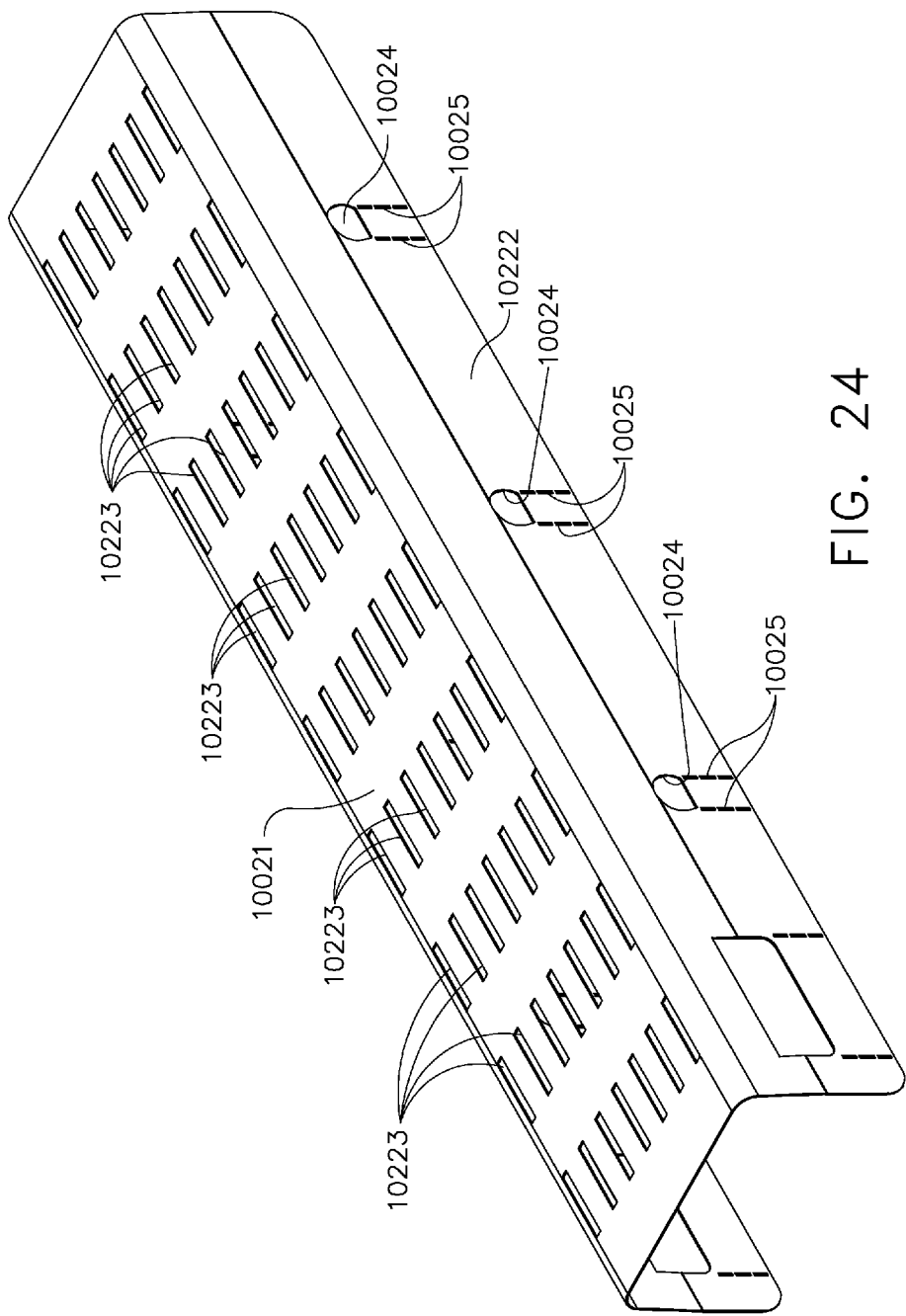


FIG. 23



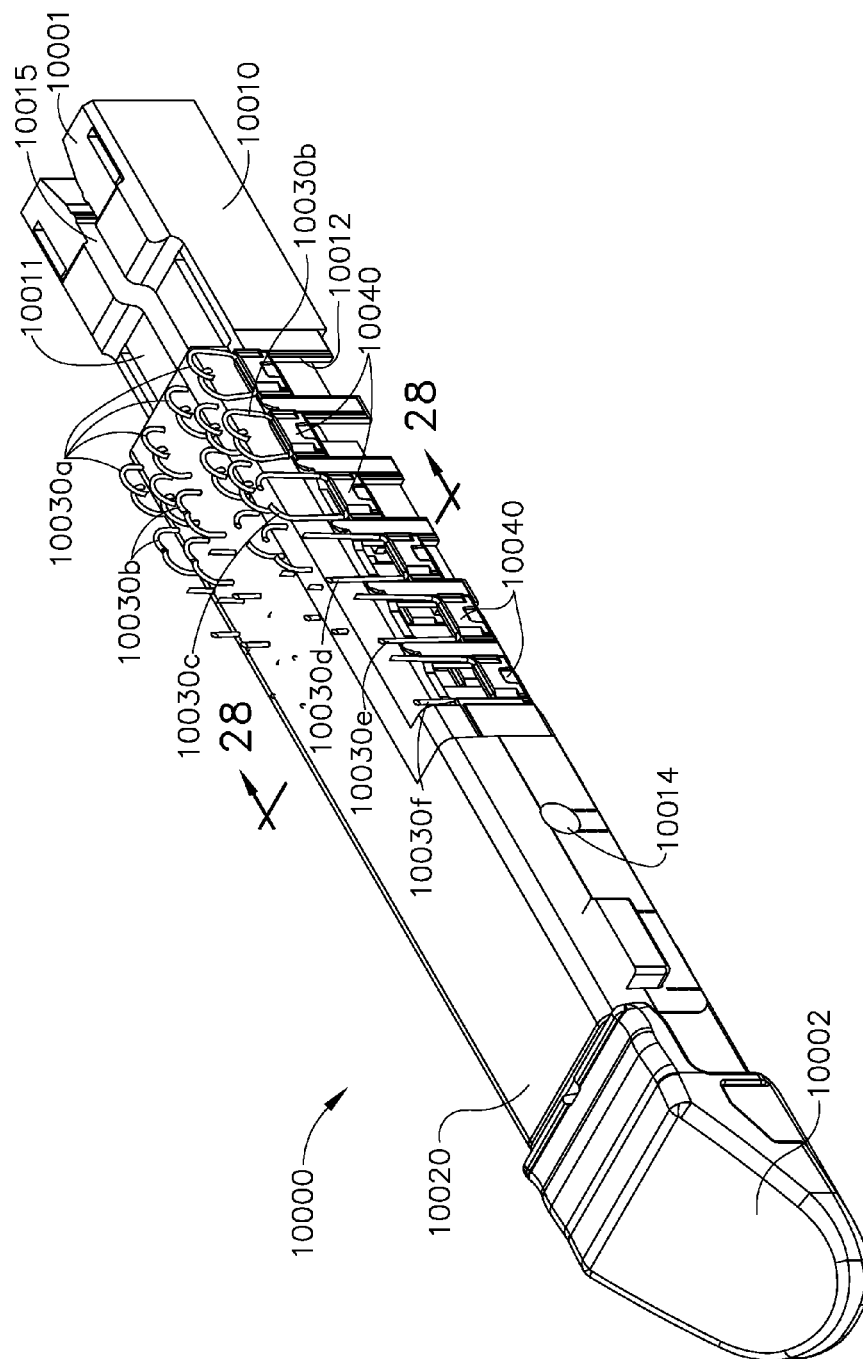


FIG. 25

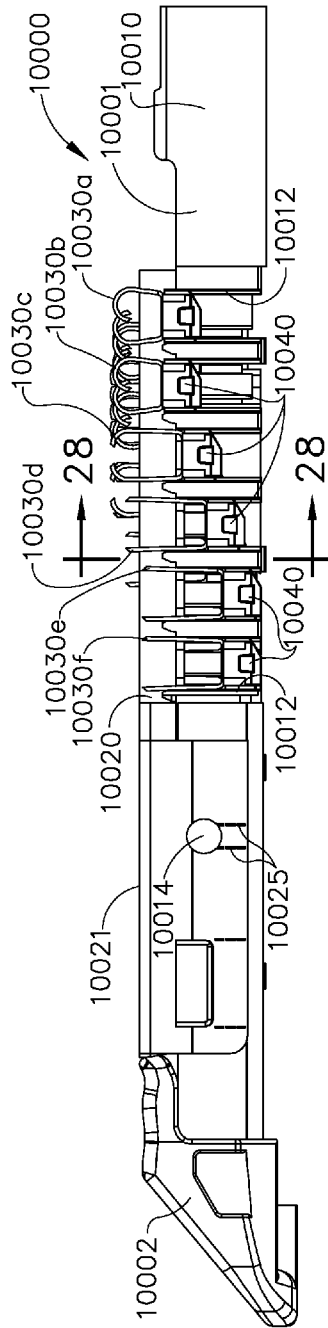


FIG. 26

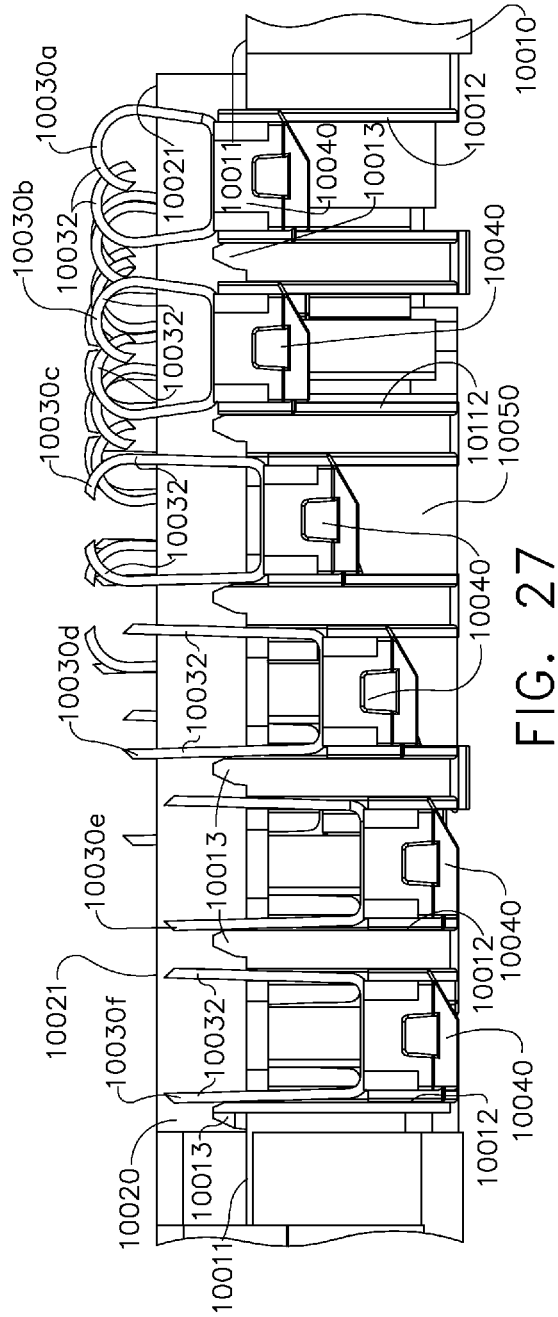
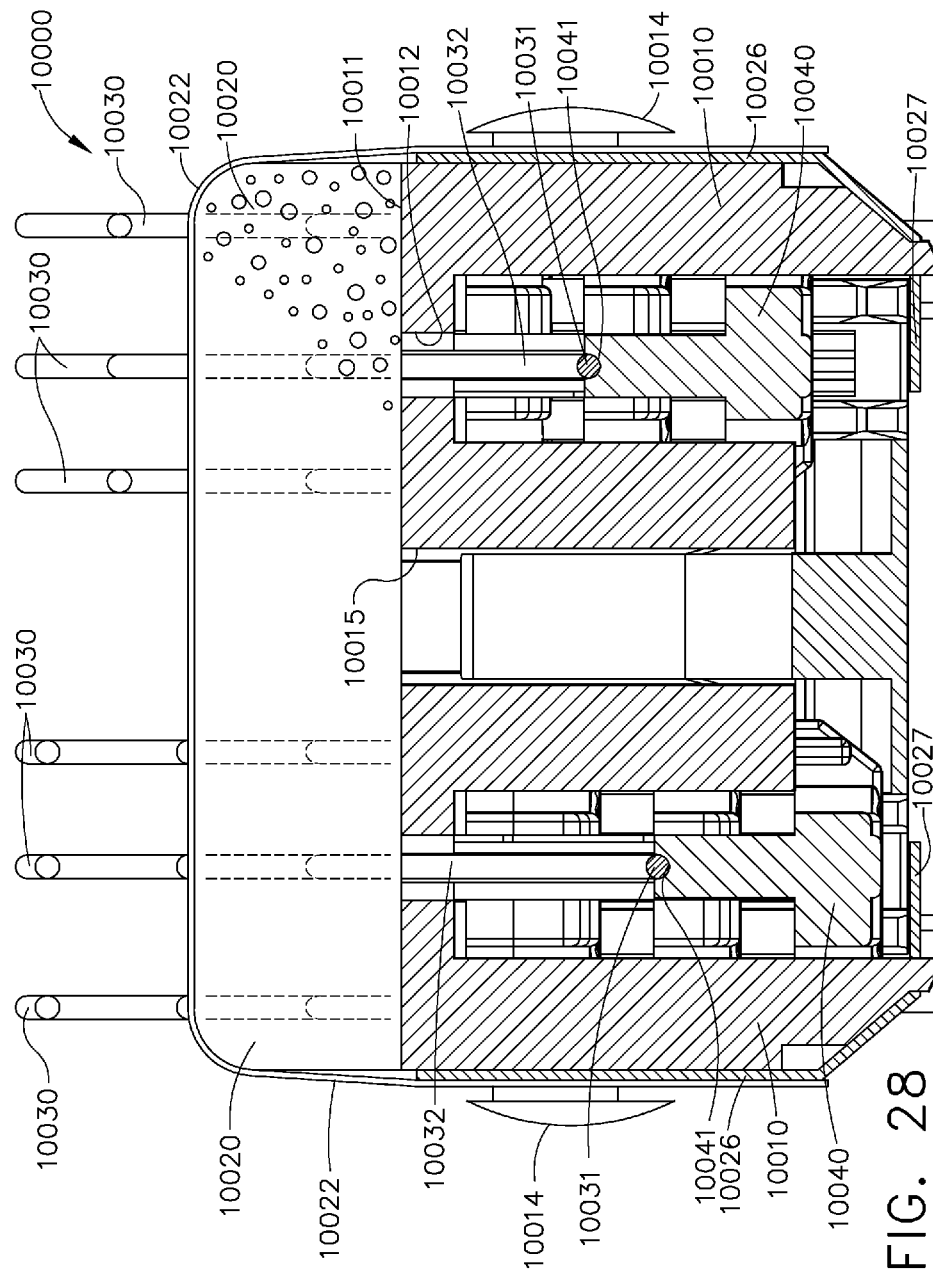


FIG. 27



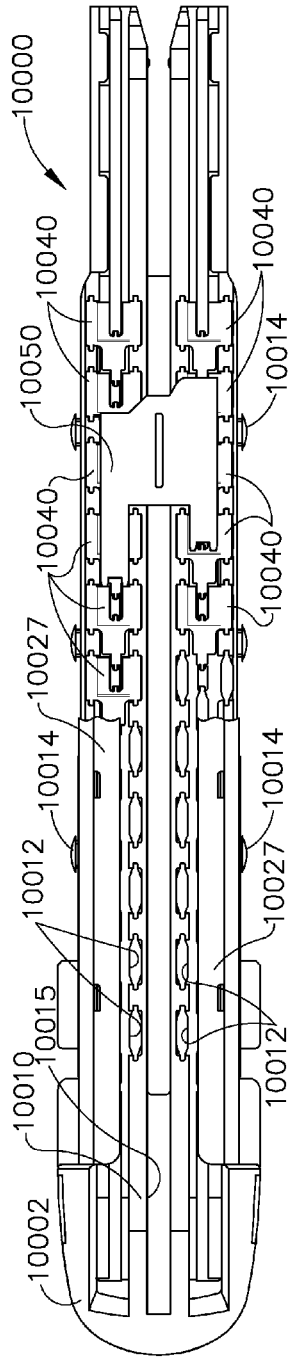


FIG. 29

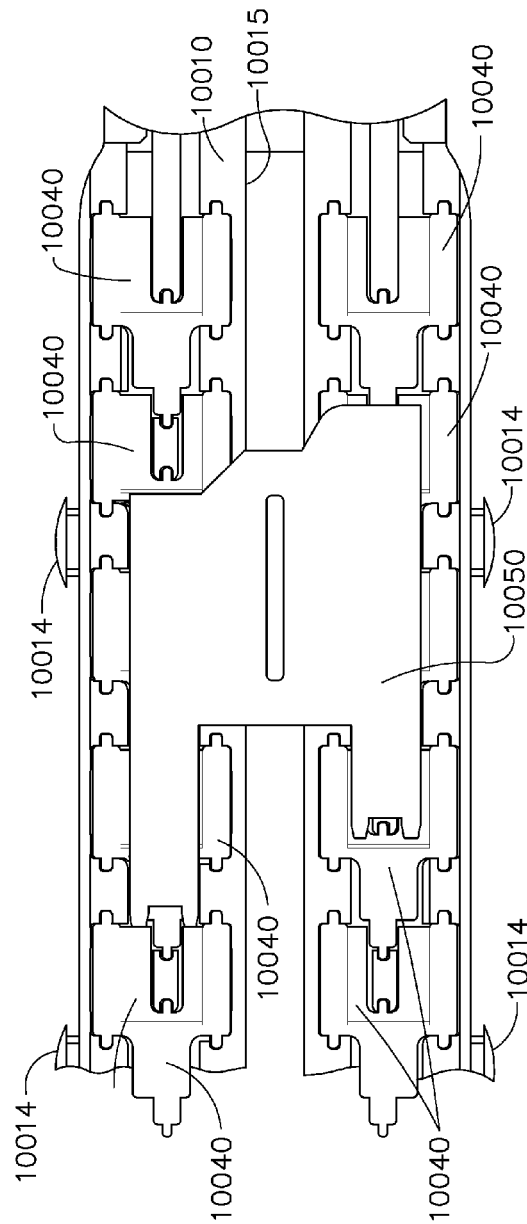
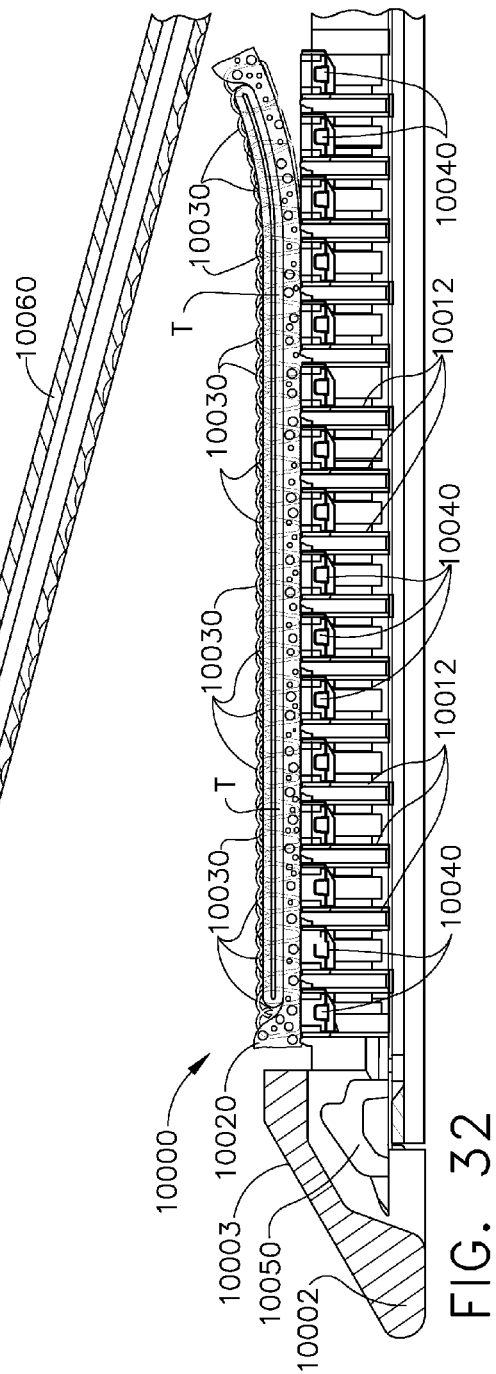
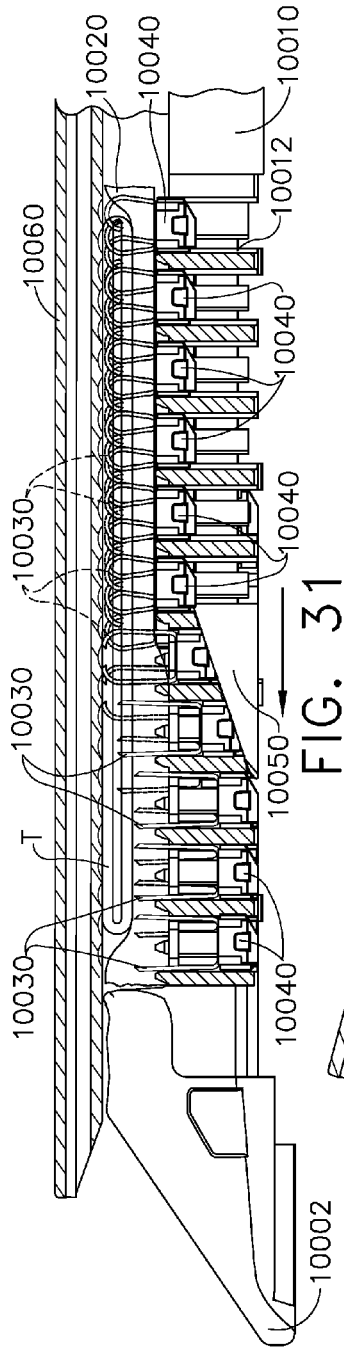


FIG. 30





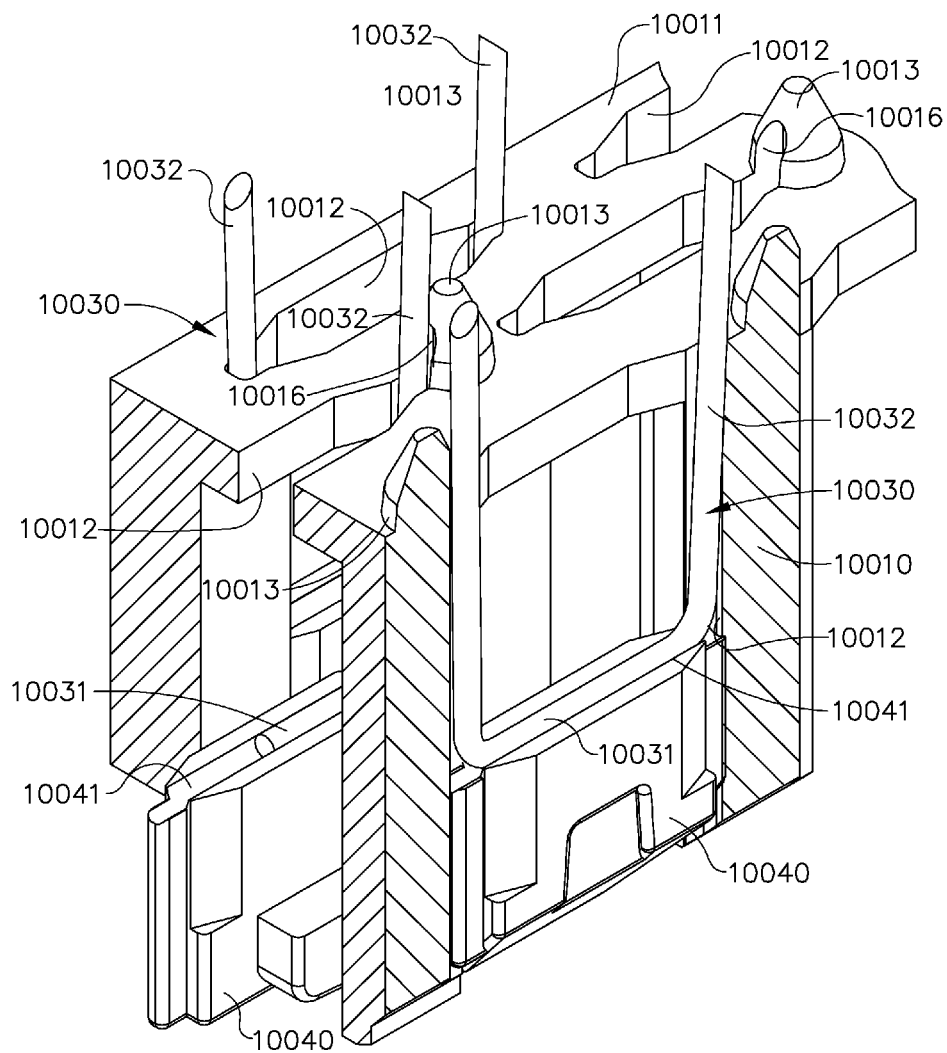


FIG. 33

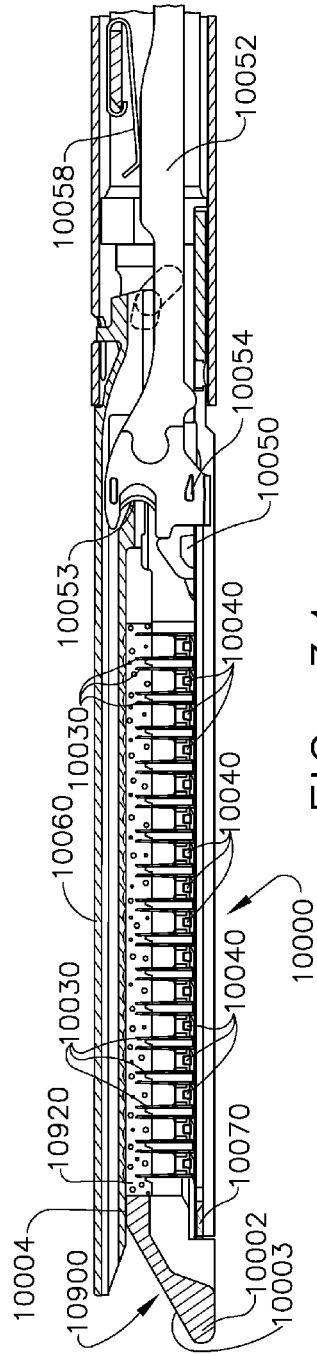


FIG. 34

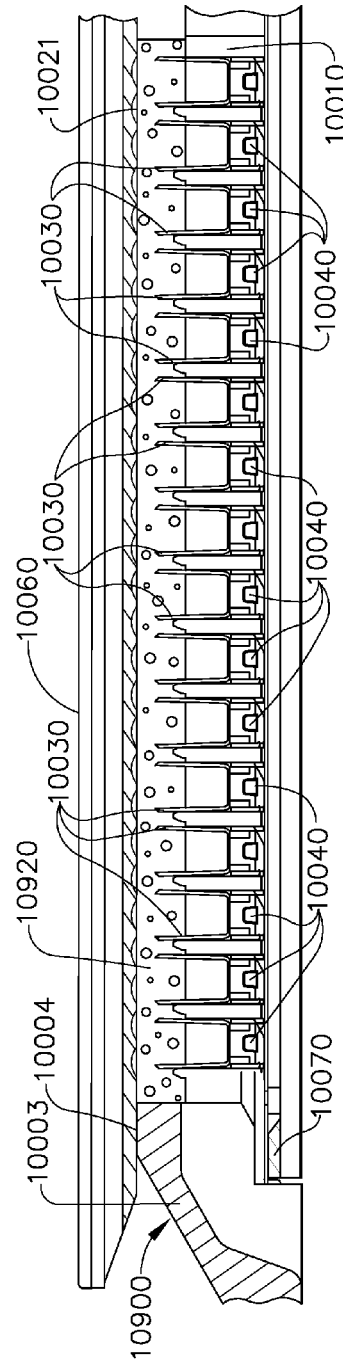


FIG. 35

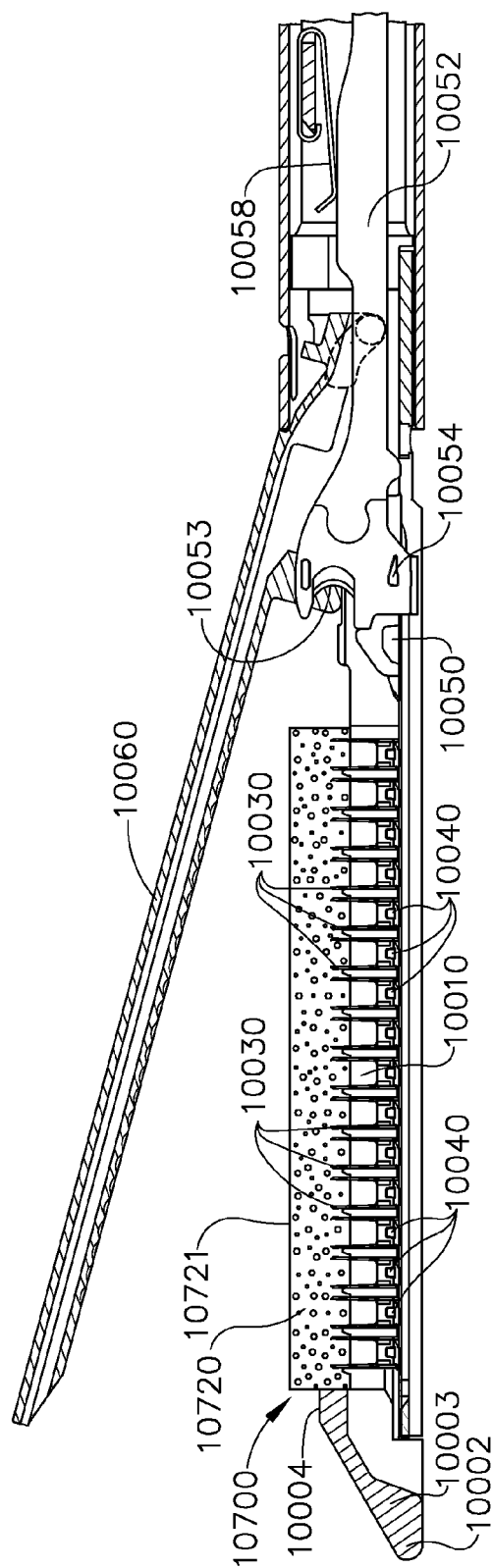


FIG. 36

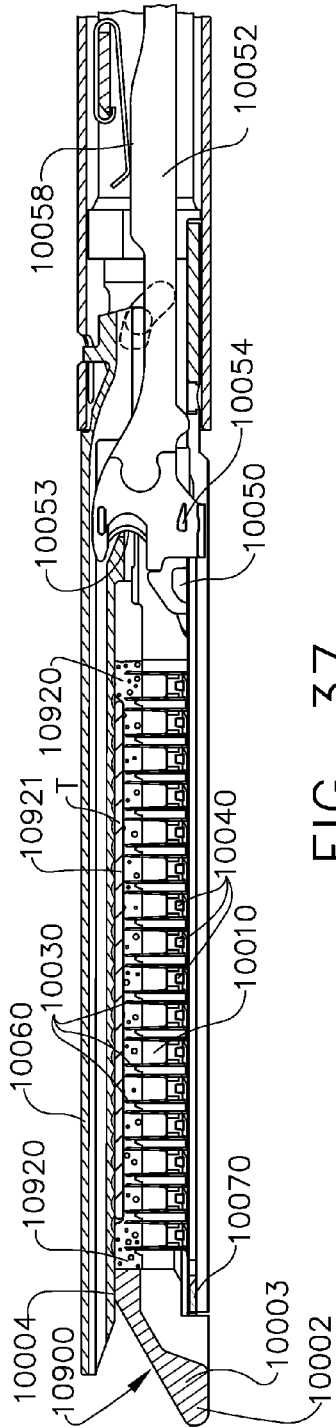


FIG. 37

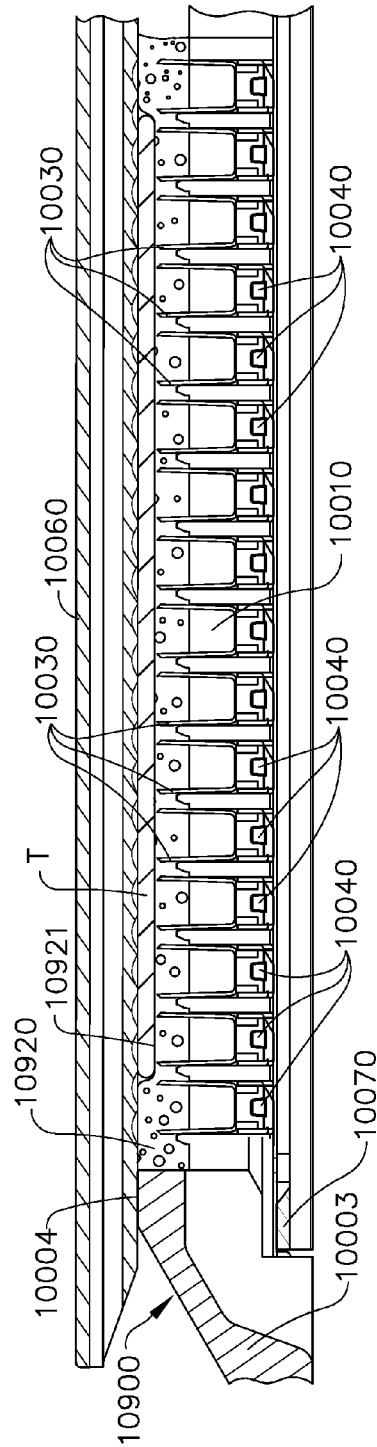


FIG. 38

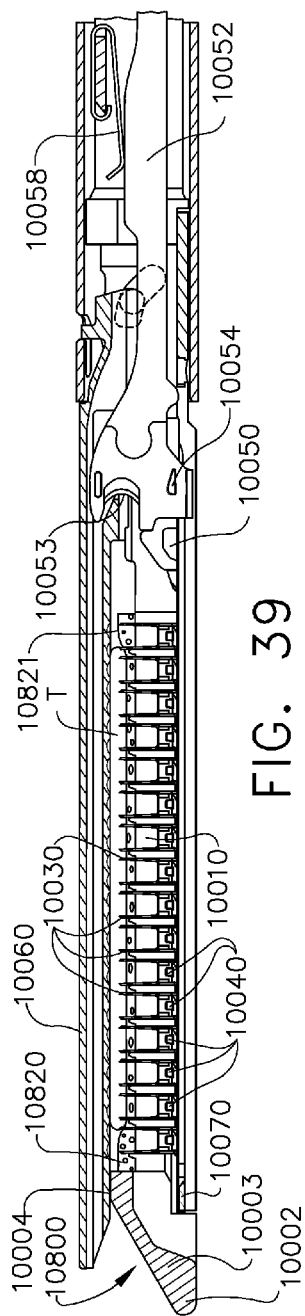


FIG. 39

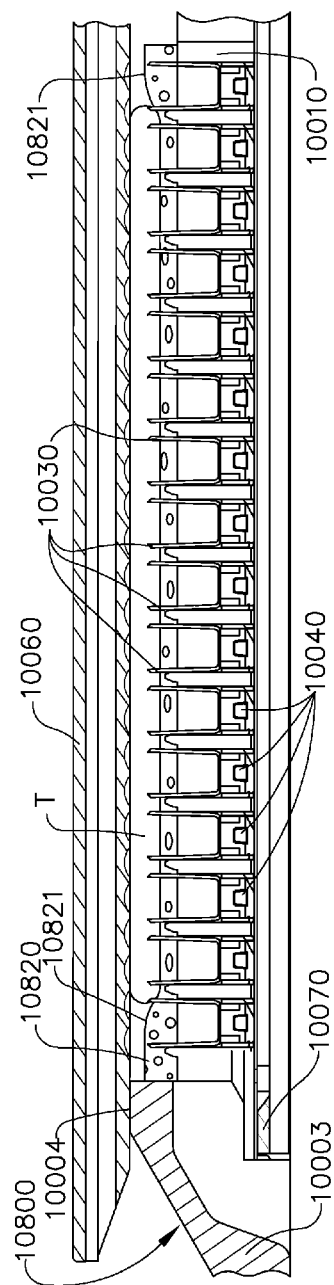


FIG. 40

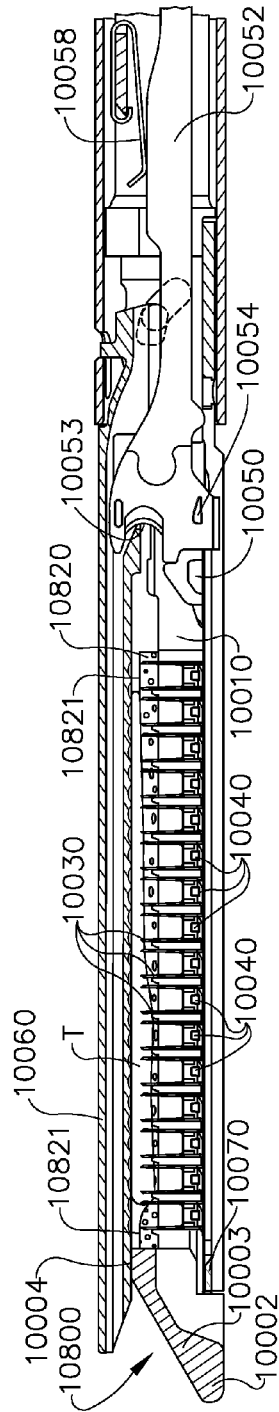


FIG. 41

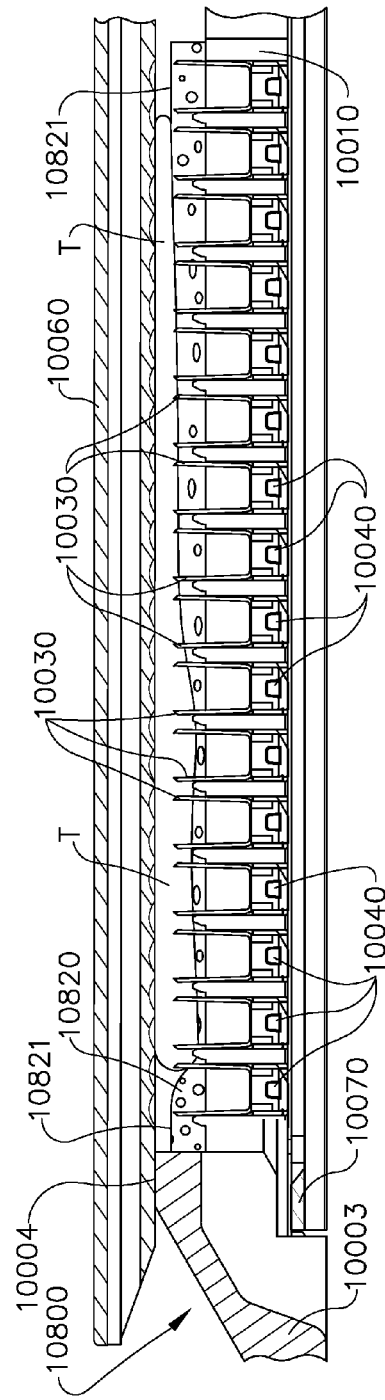


FIG. 42

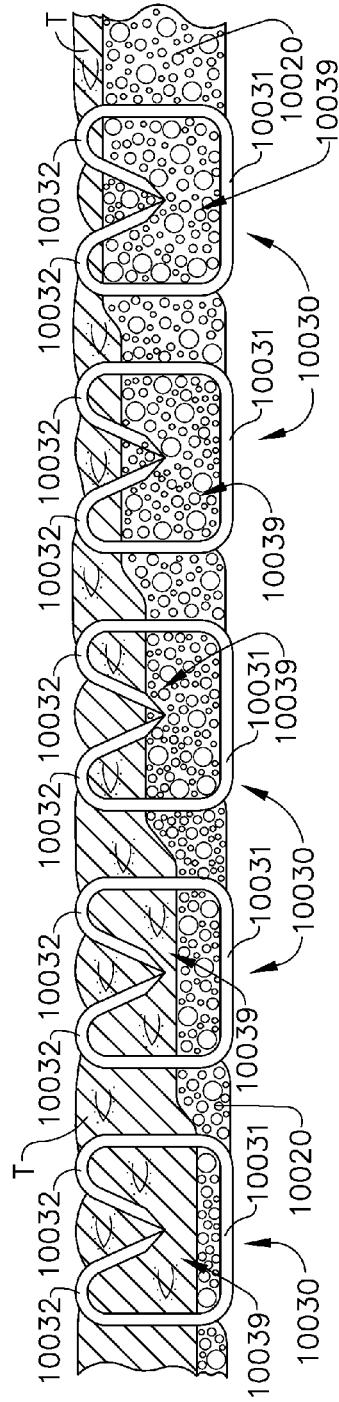


FIG. 43

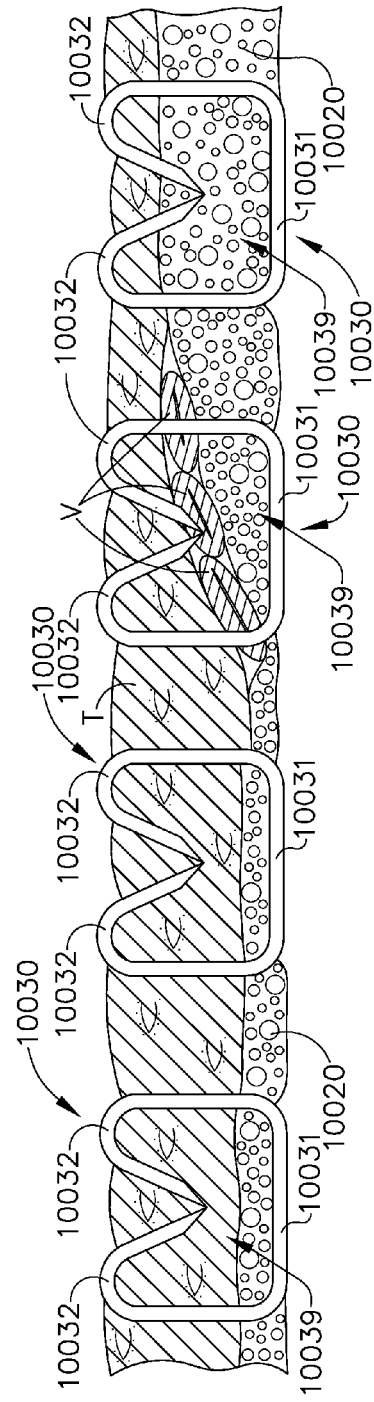


FIG. 44



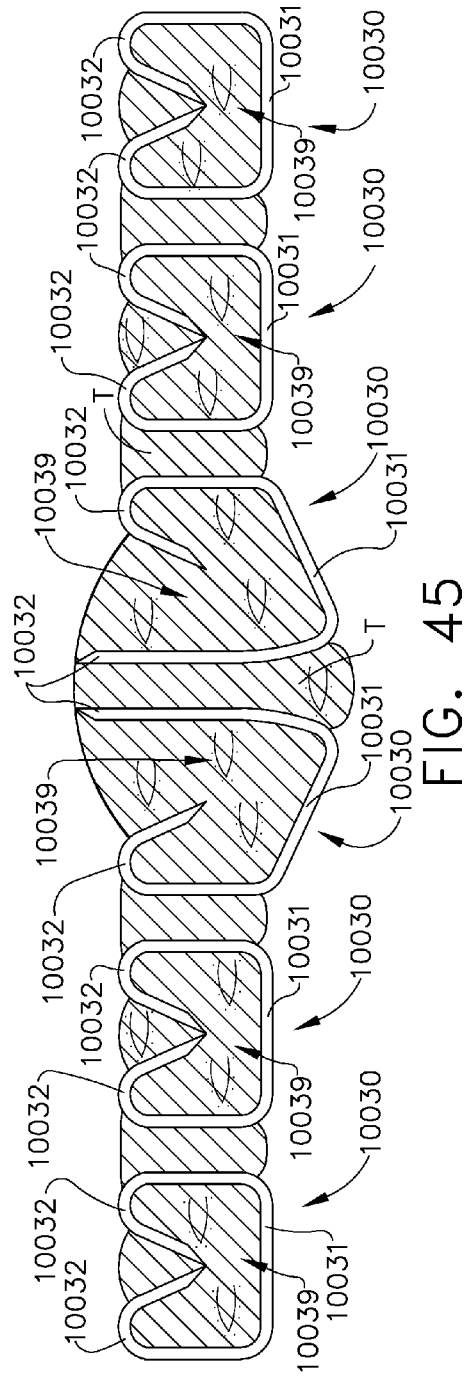


FIG. 45

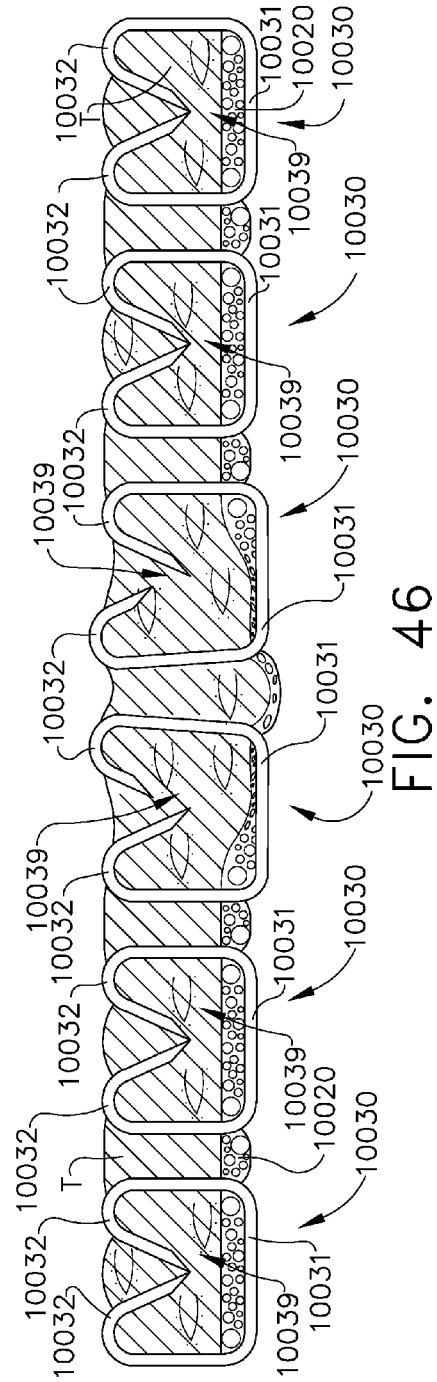


FIG. 46

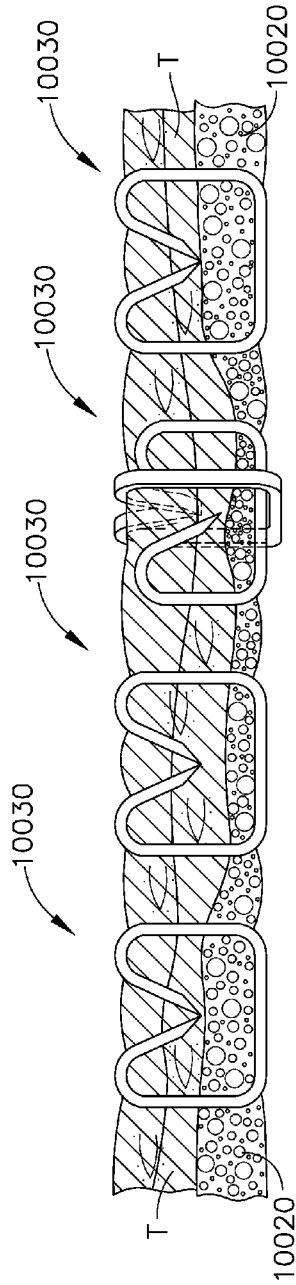


FIG. 47

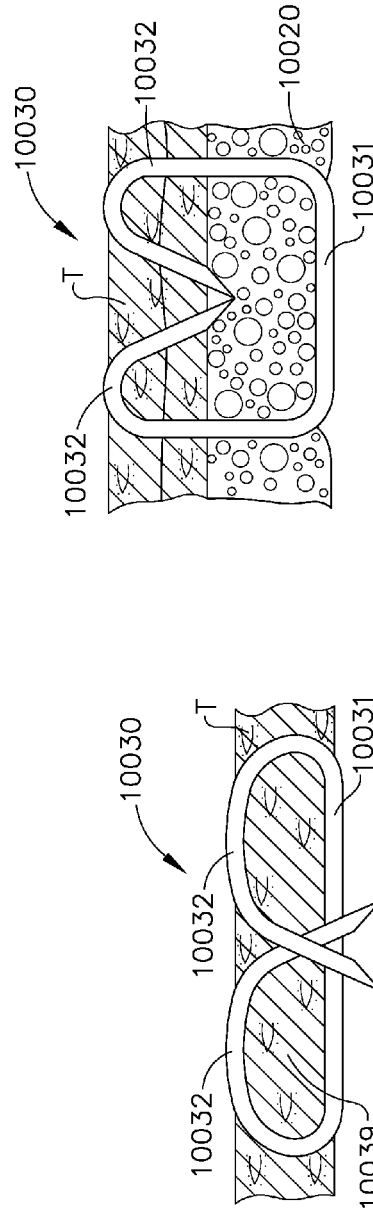


FIG. 48

FIG. 49

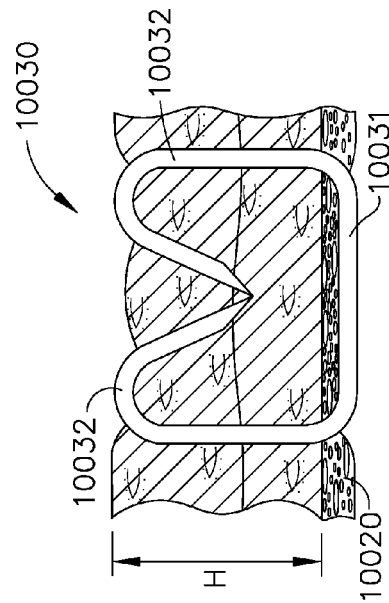


FIG. 50

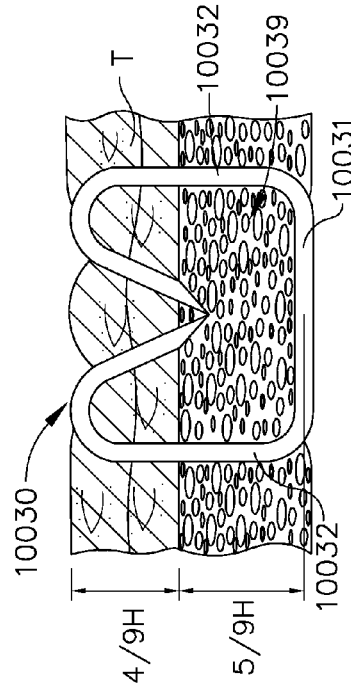


FIG. 51

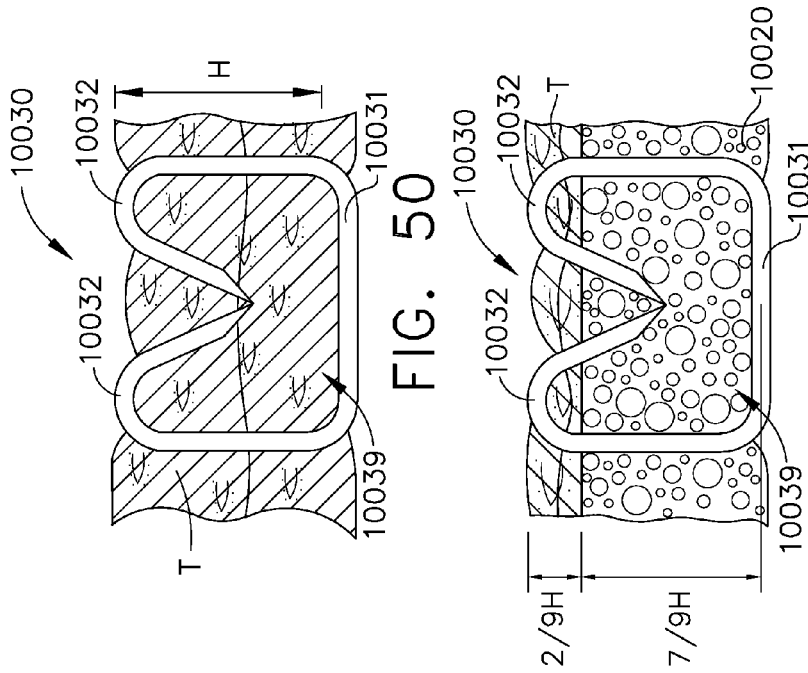


FIG. 52

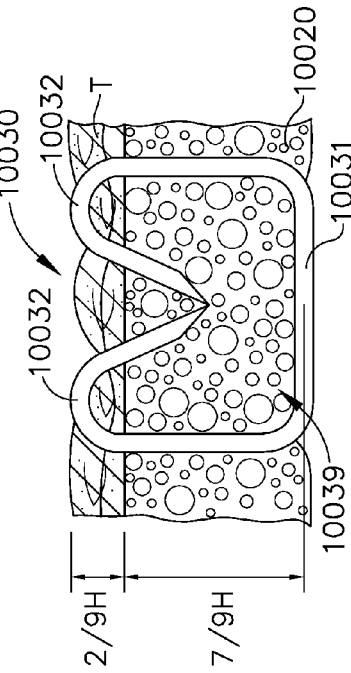


FIG. 53

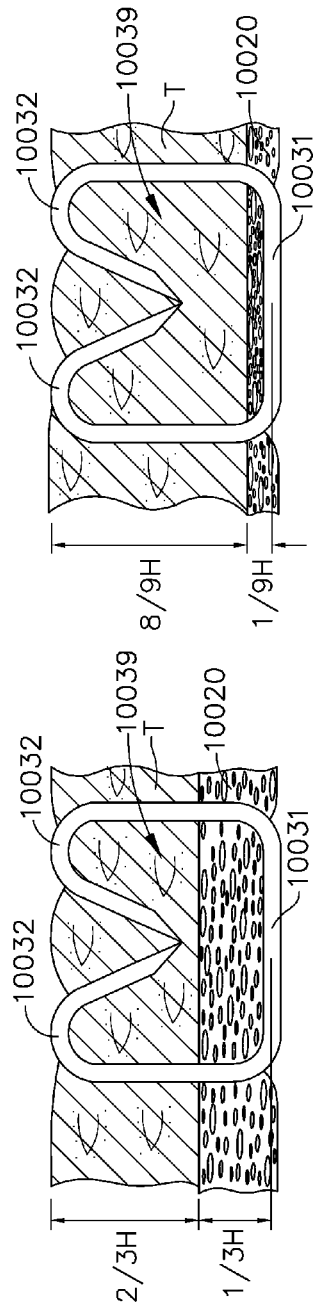


FIG. 55

FIG. 54

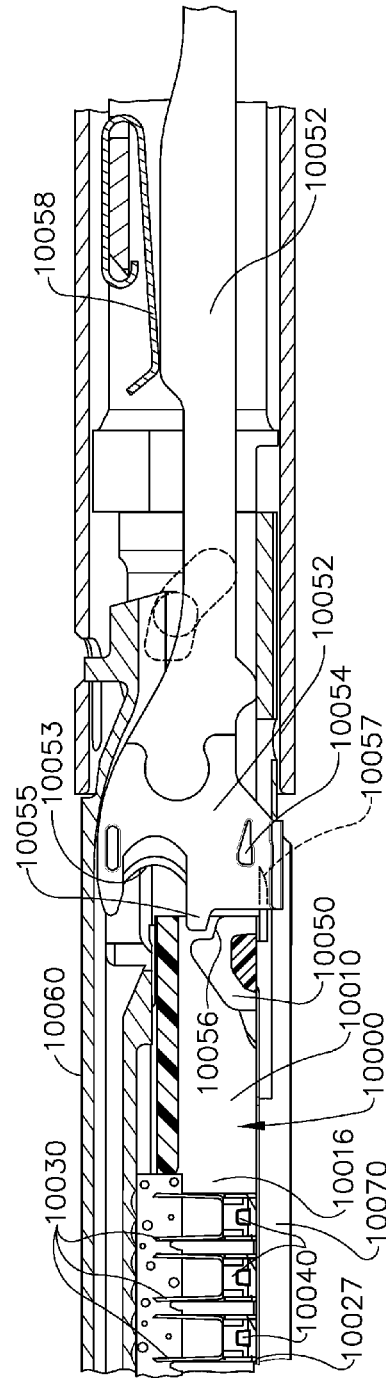


FIG. 56

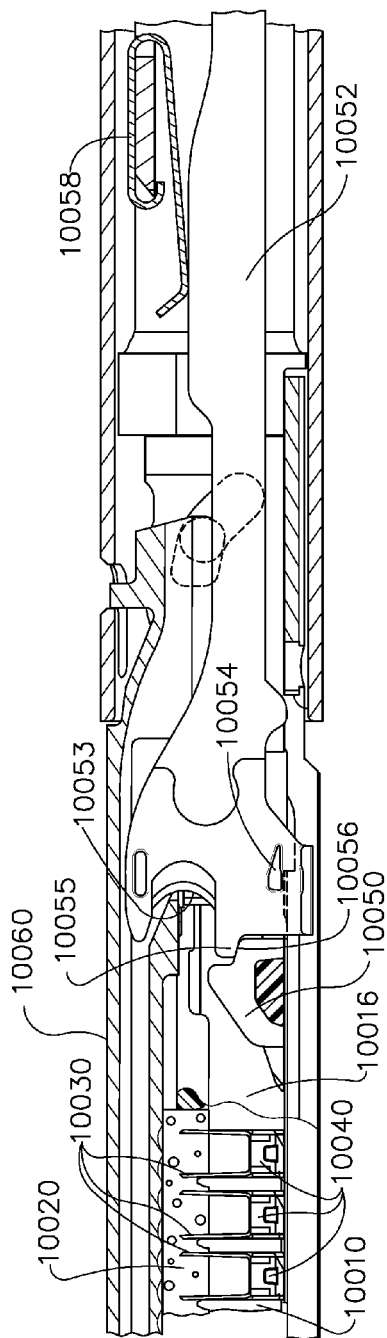


FIG. 57

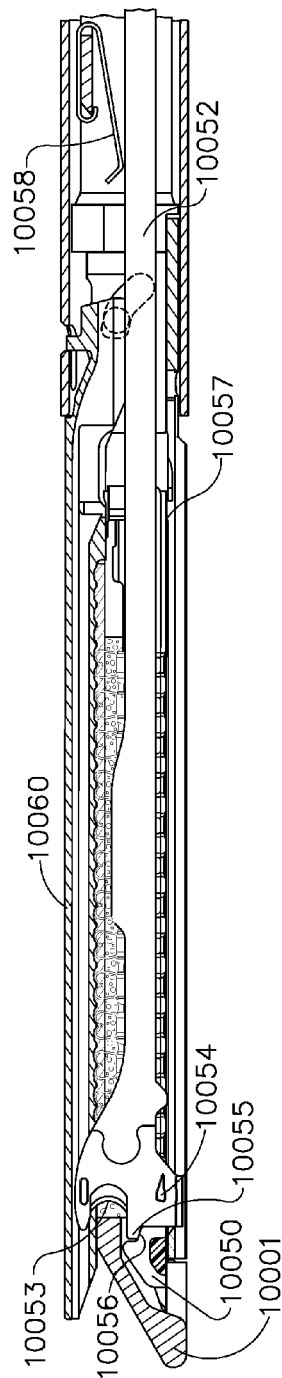


FIG. 58

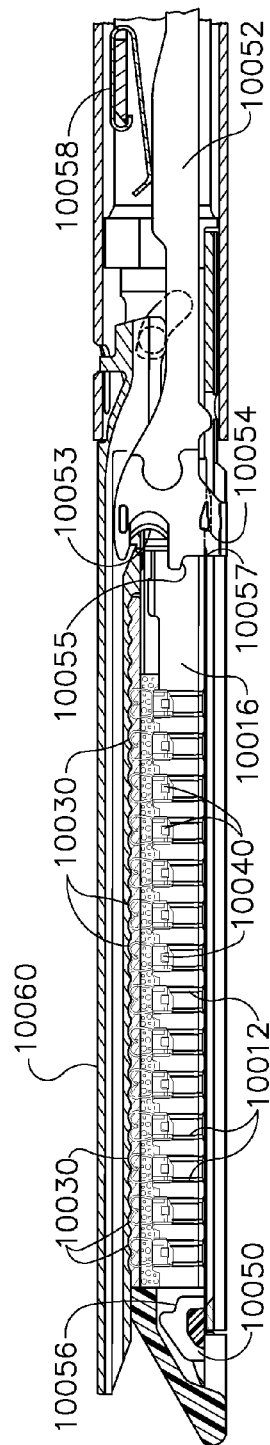


FIG. 59

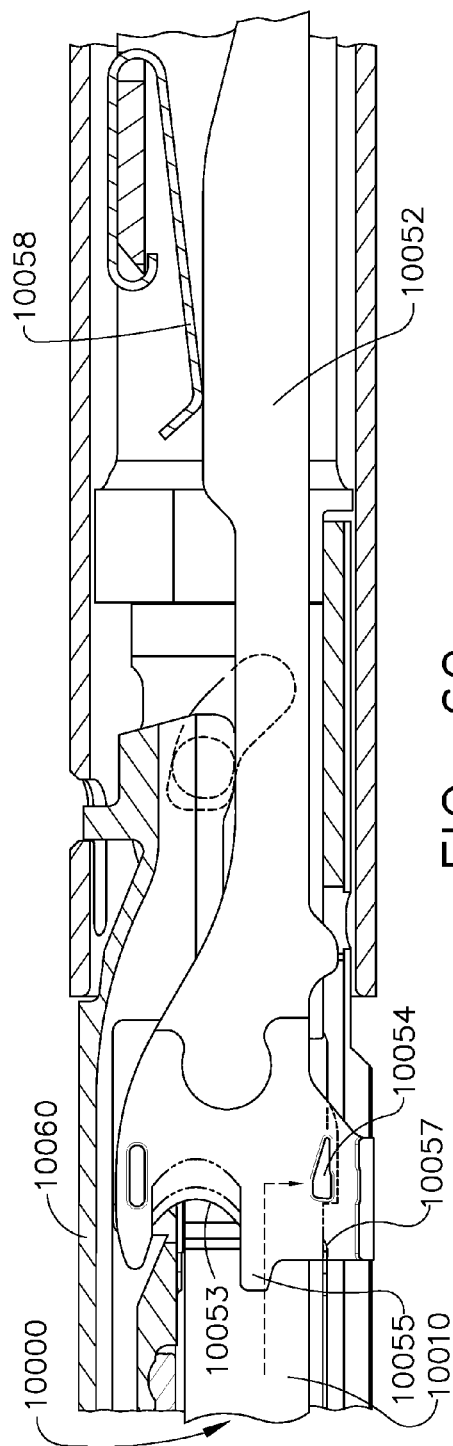


FIG. 60

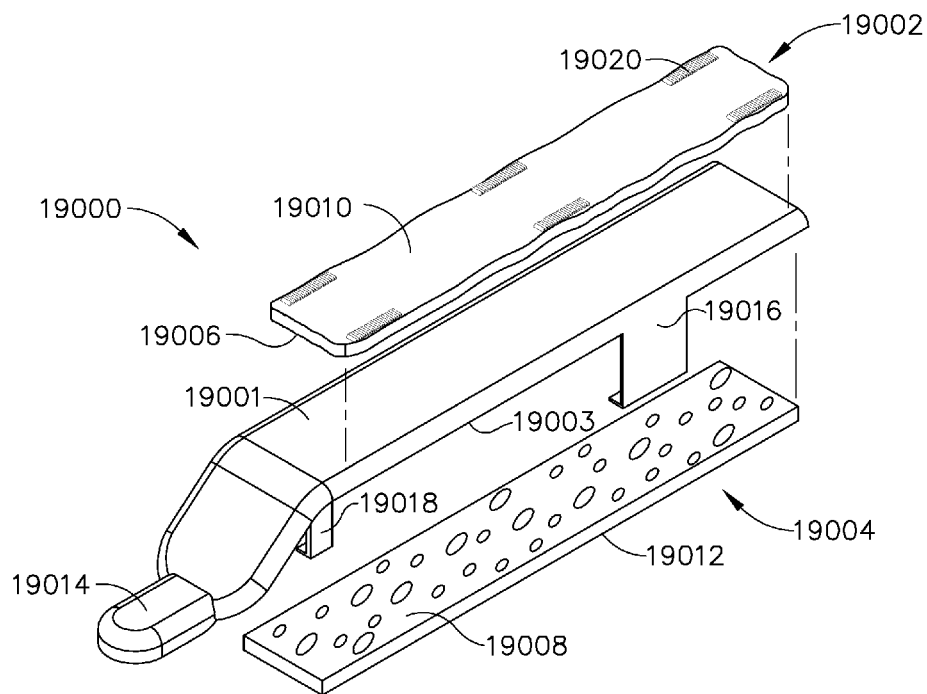


FIG. 61

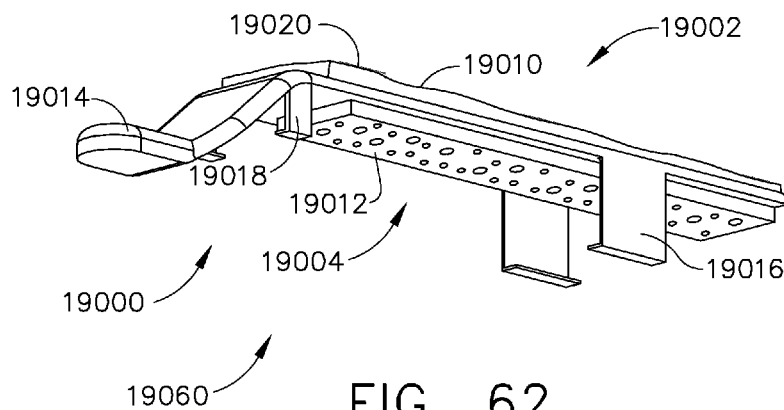


FIG. 62

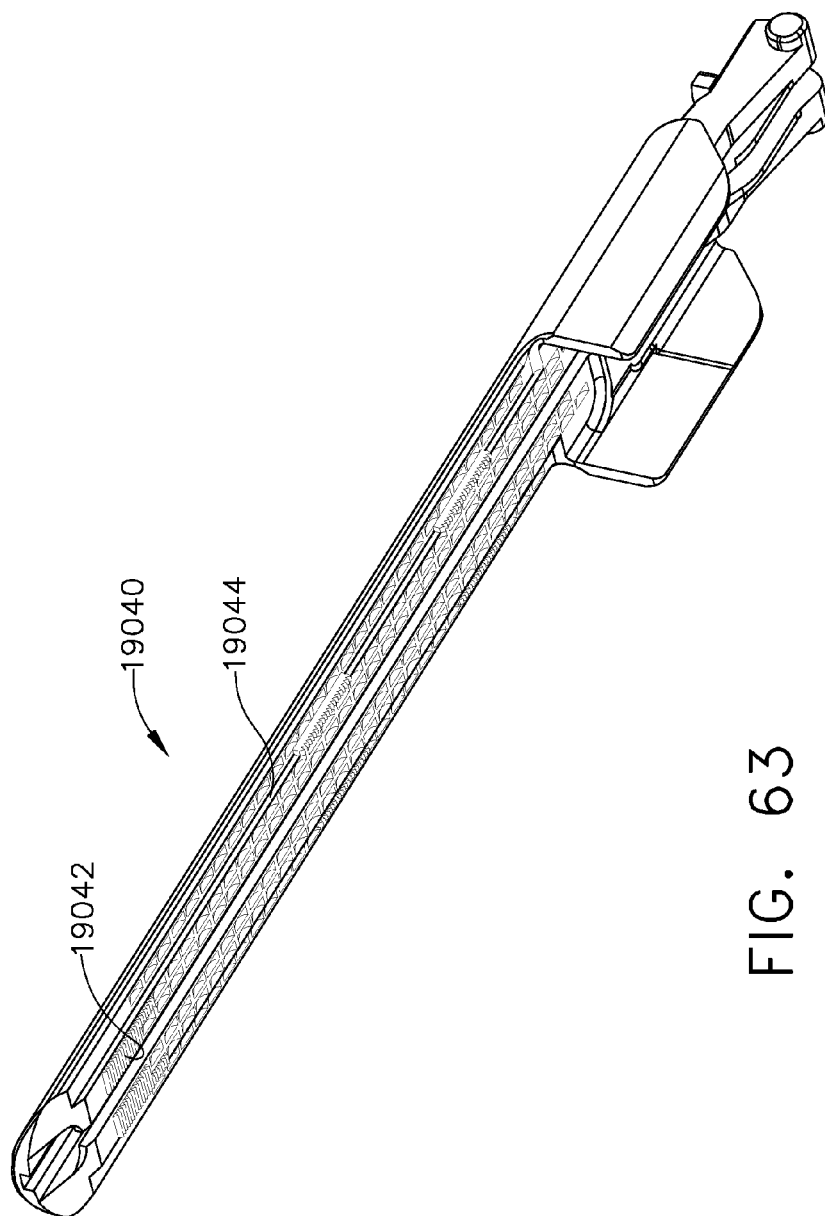


FIG. 63



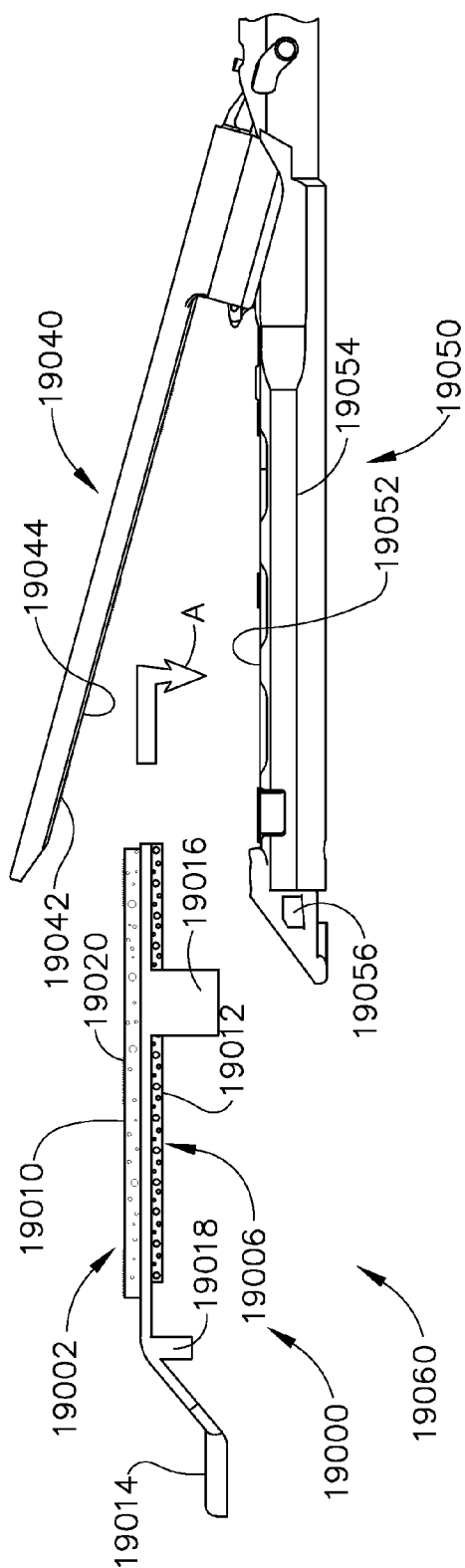
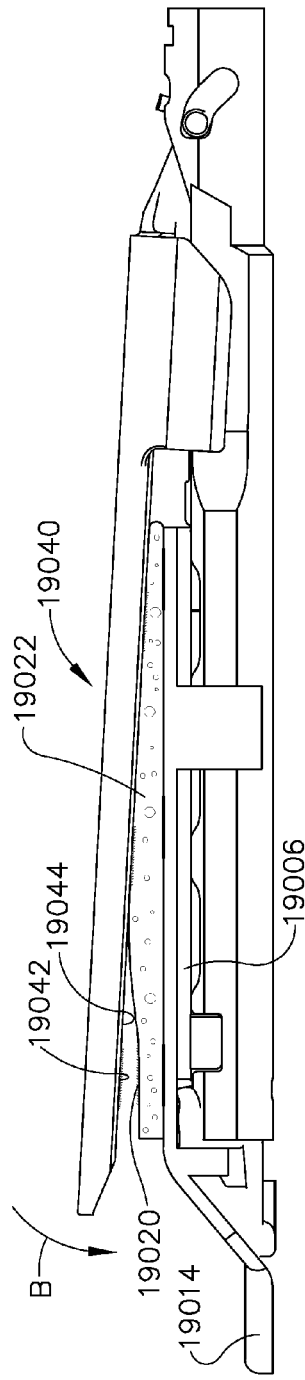
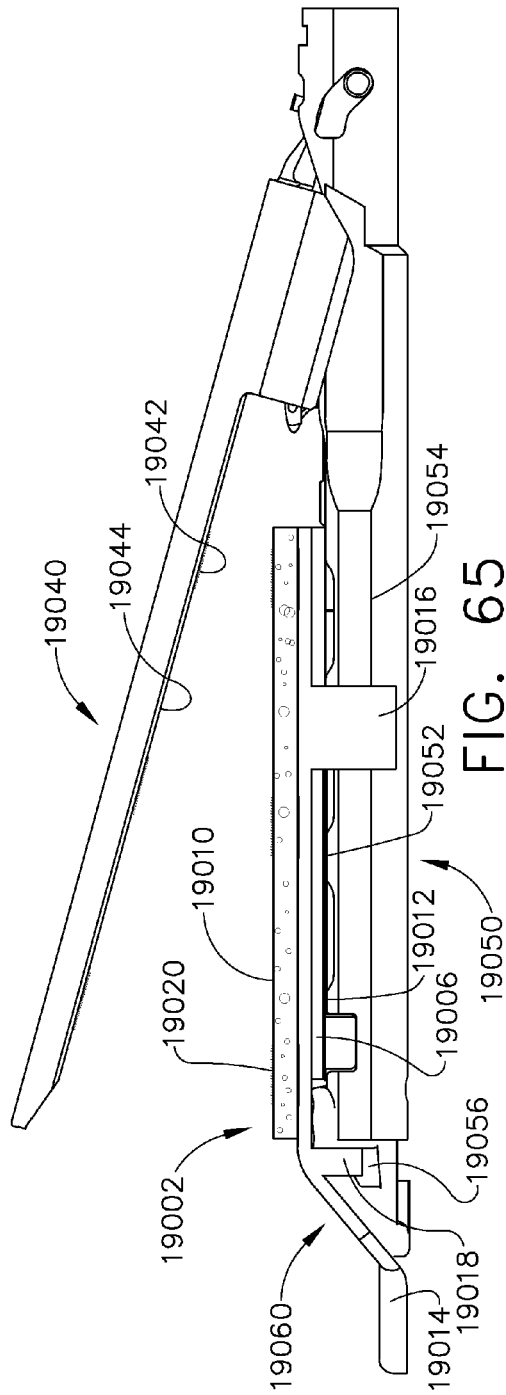


FIG. 64



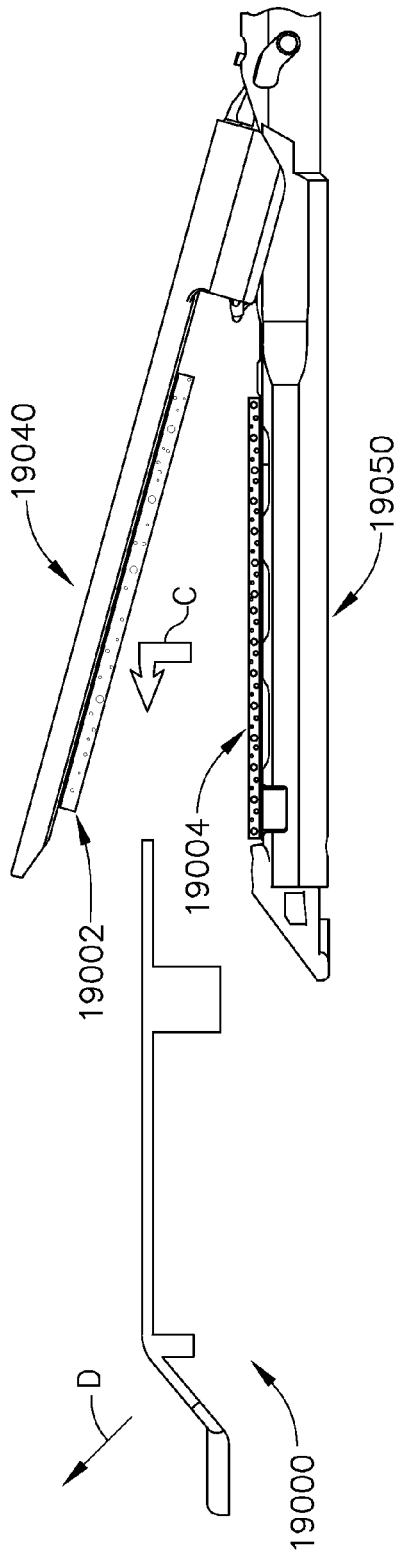


FIG. 67

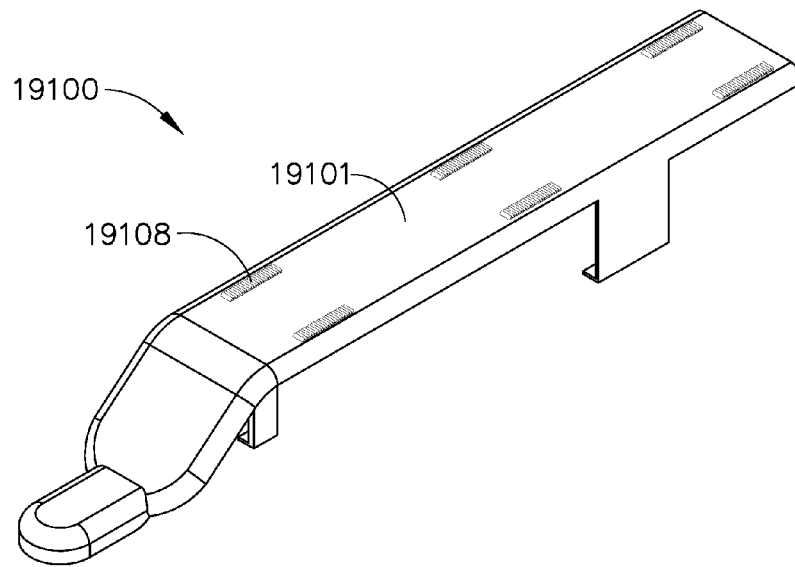
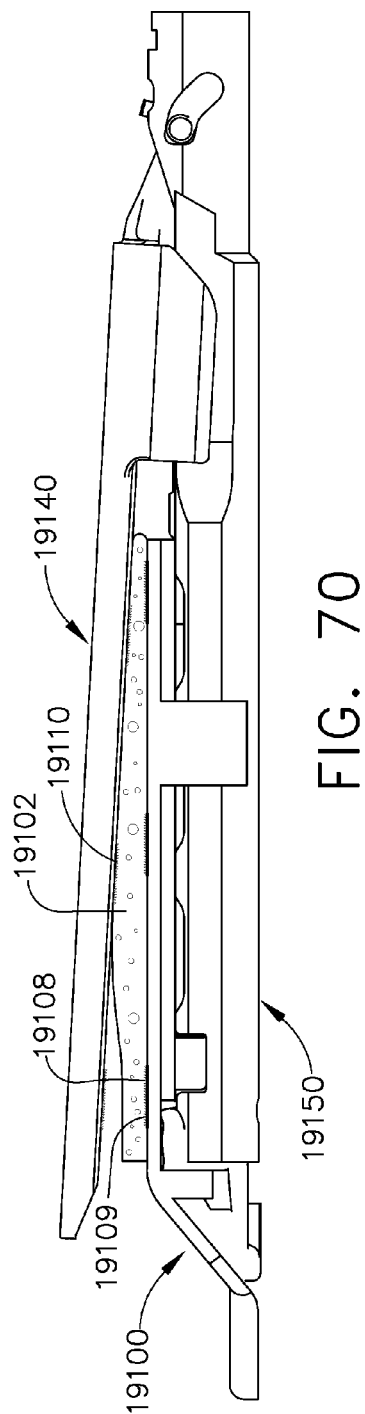
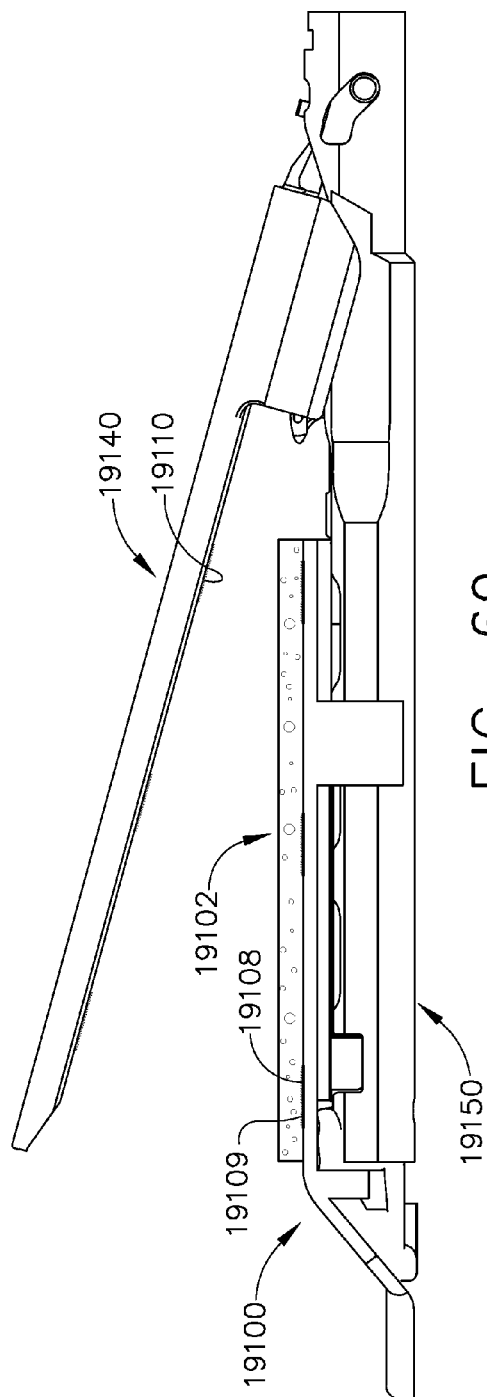


FIG. 68



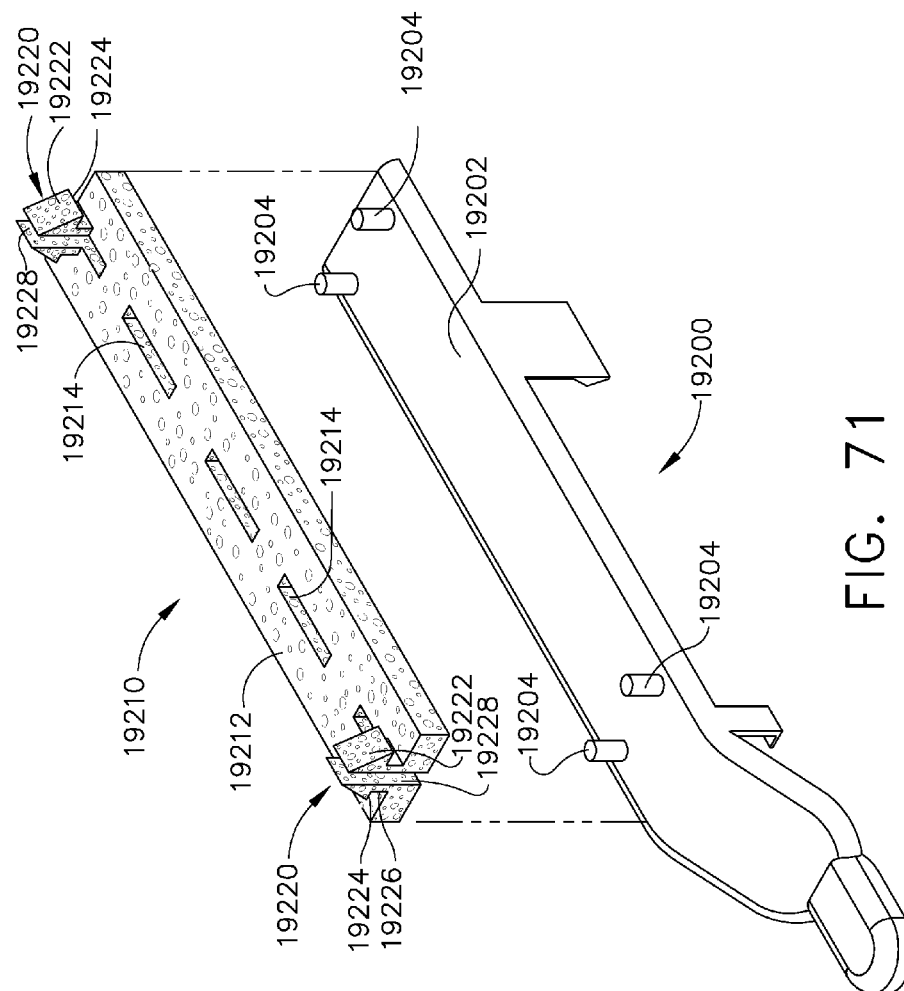


FIG. 71

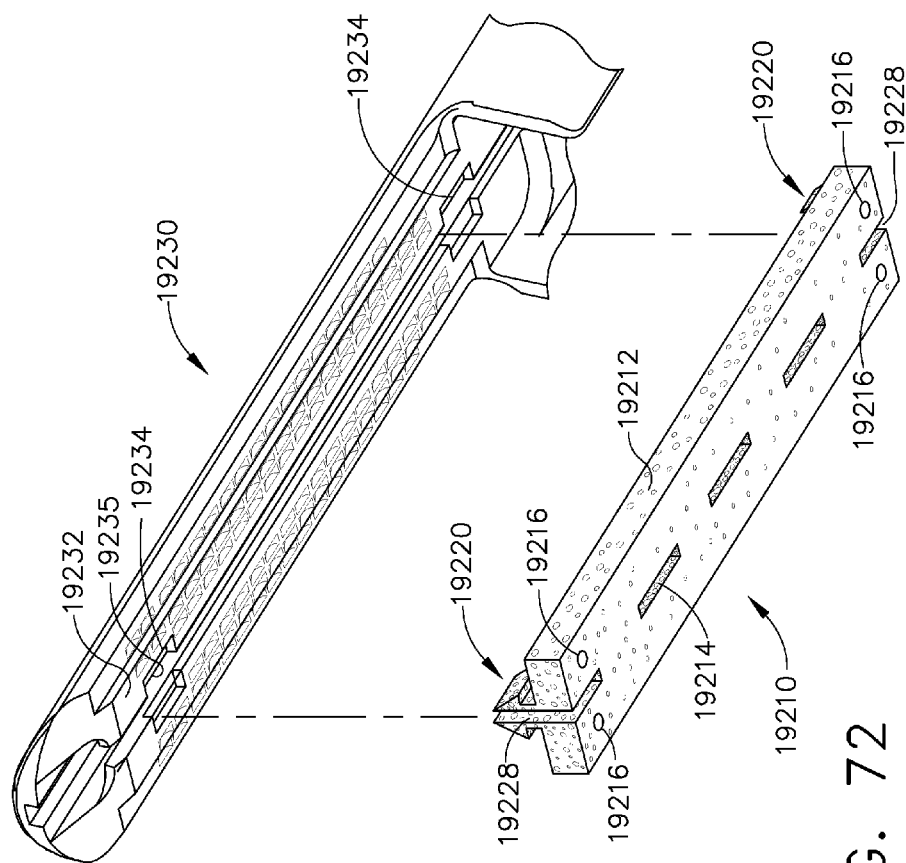


FIG. 72

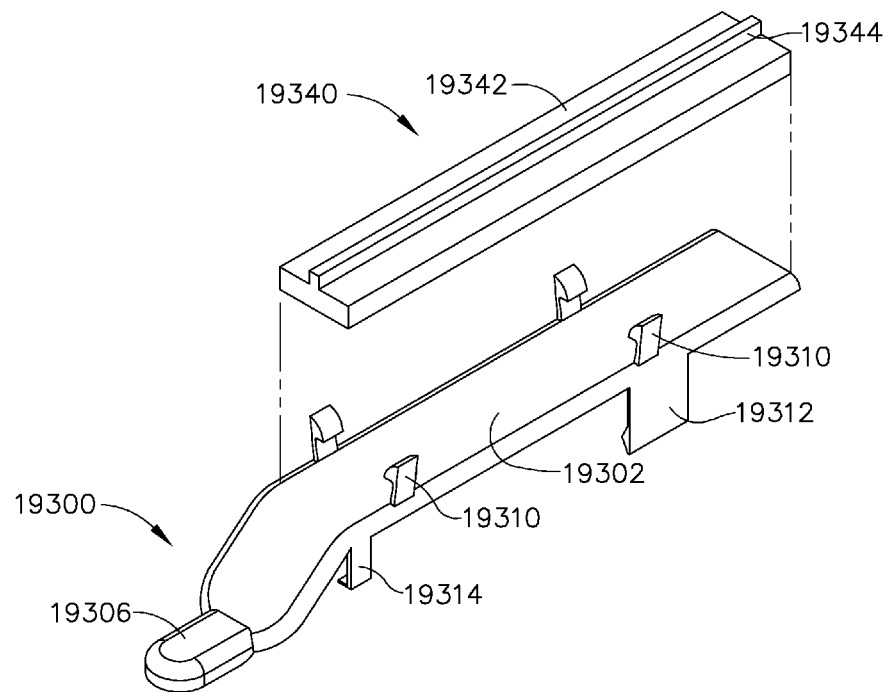


FIG. 73

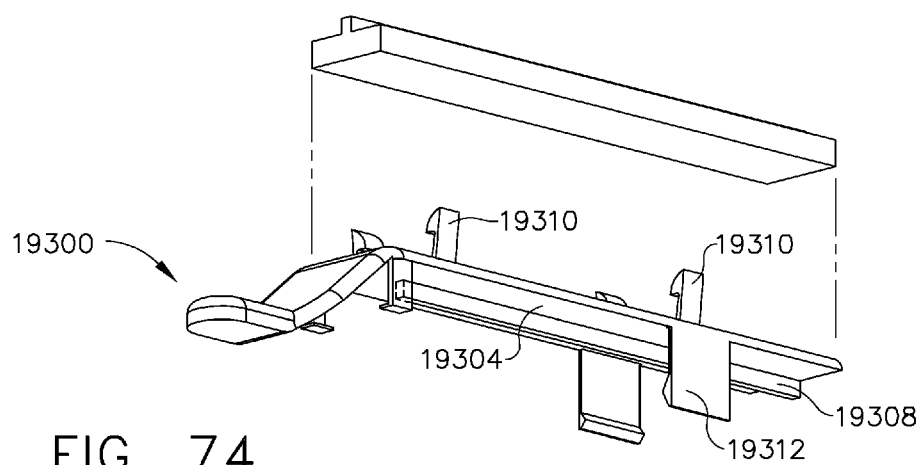
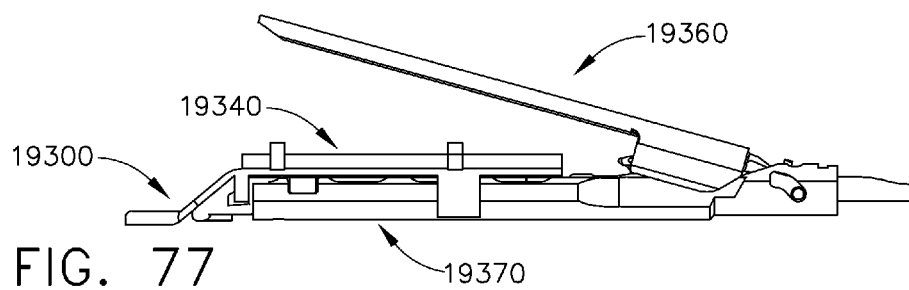
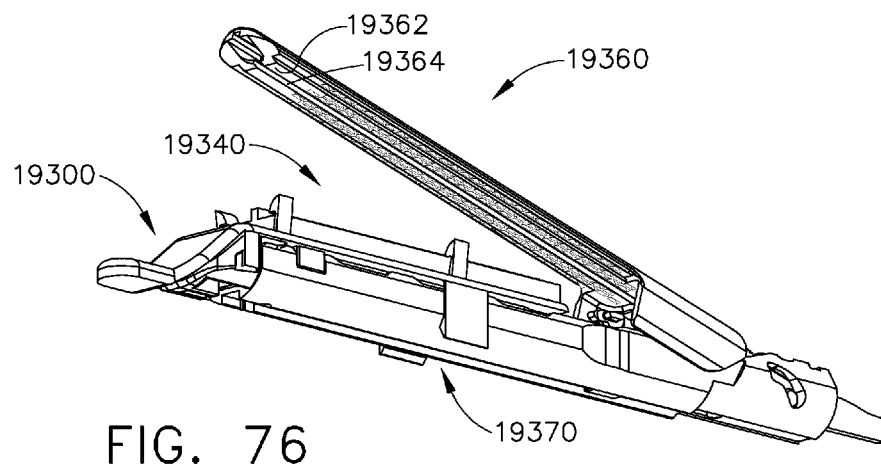
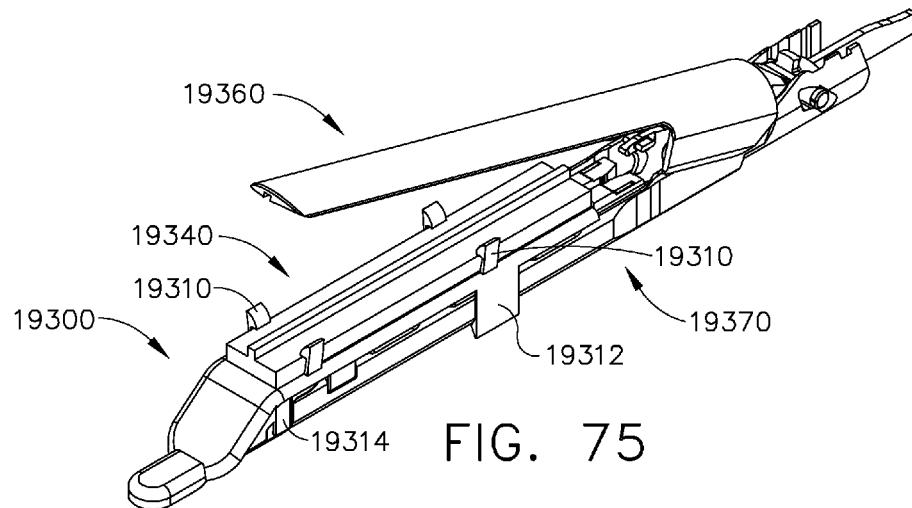
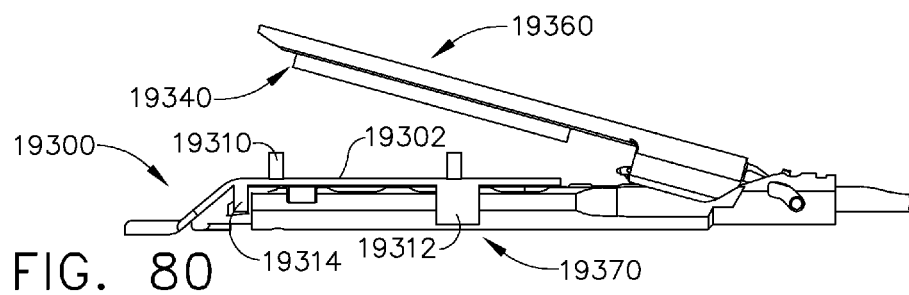
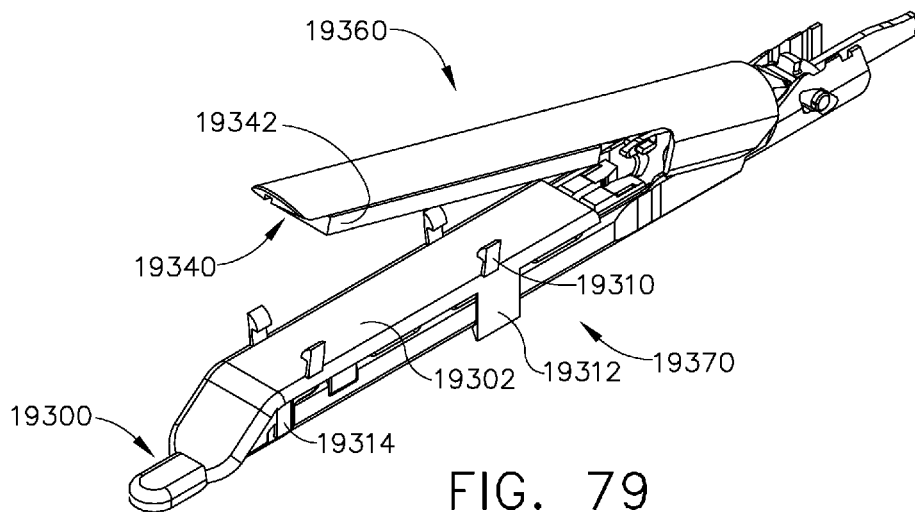
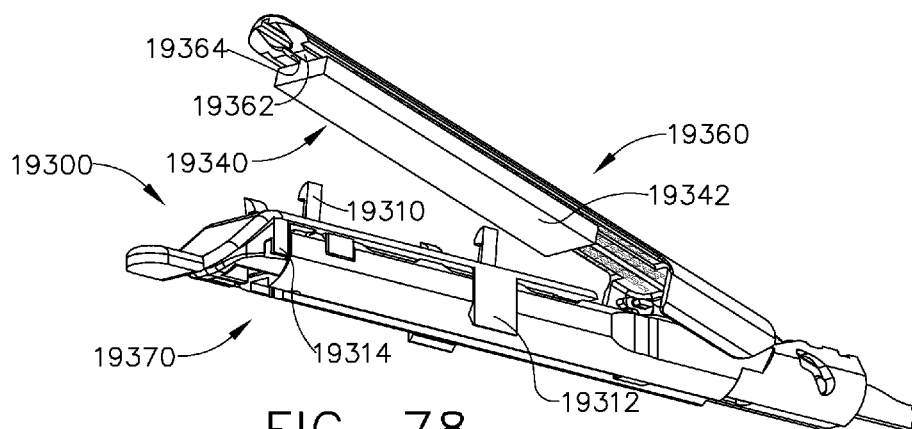


FIG. 74







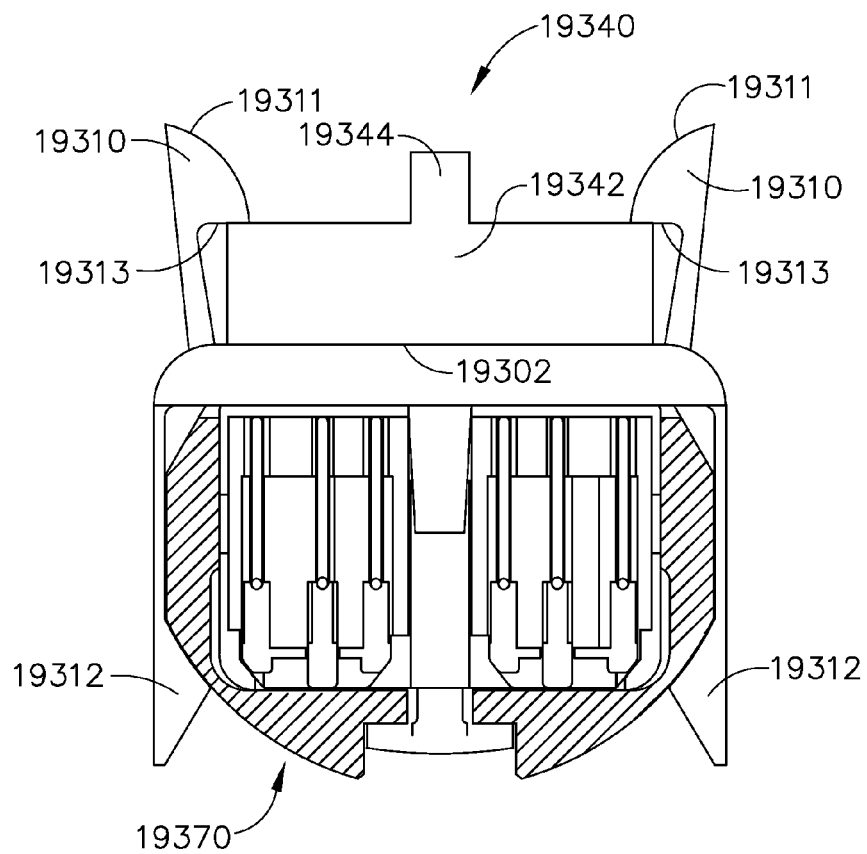


FIG. 81

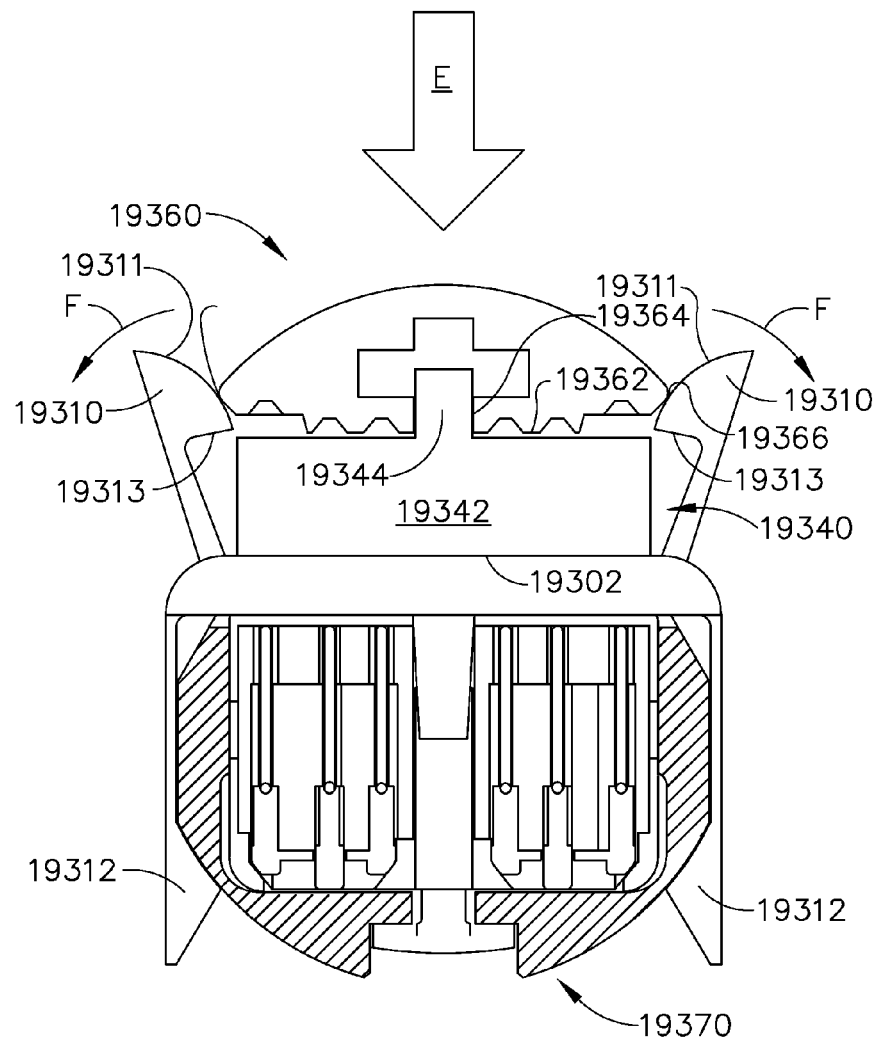


FIG. 82

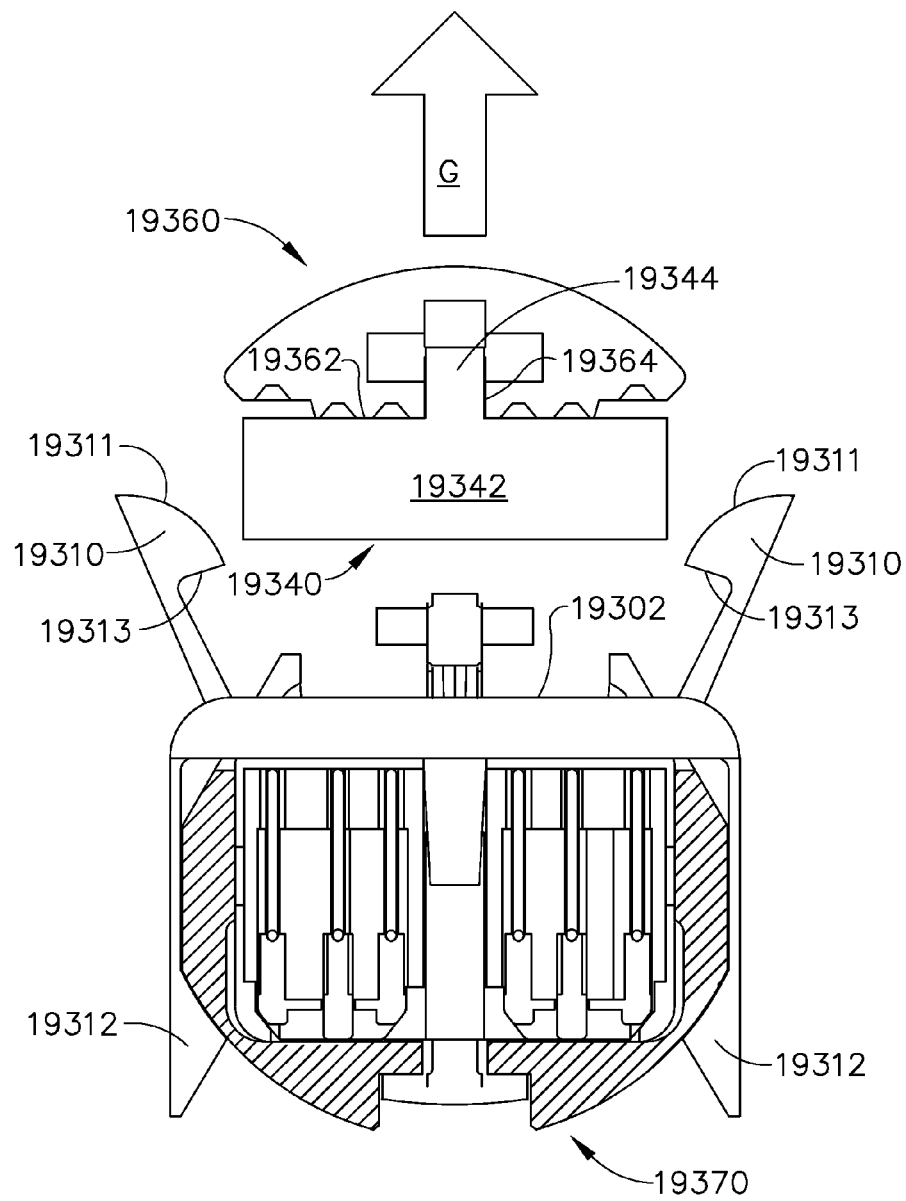


FIG. 83

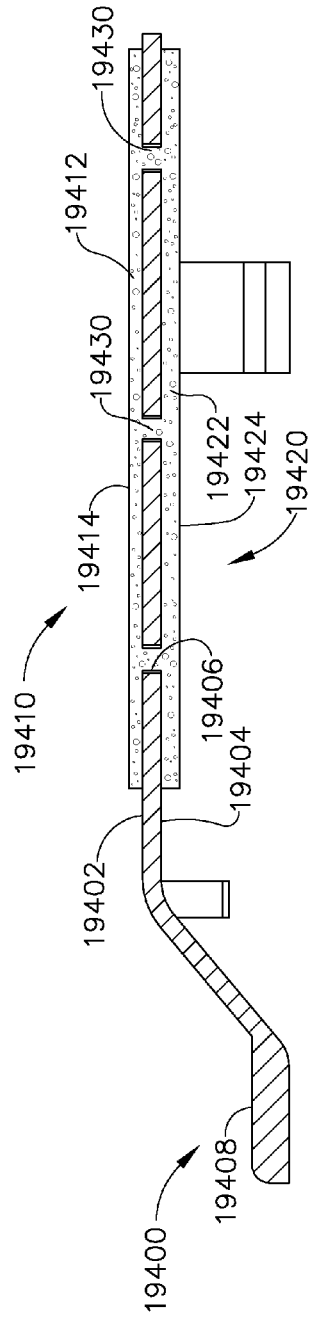


FIG. 84

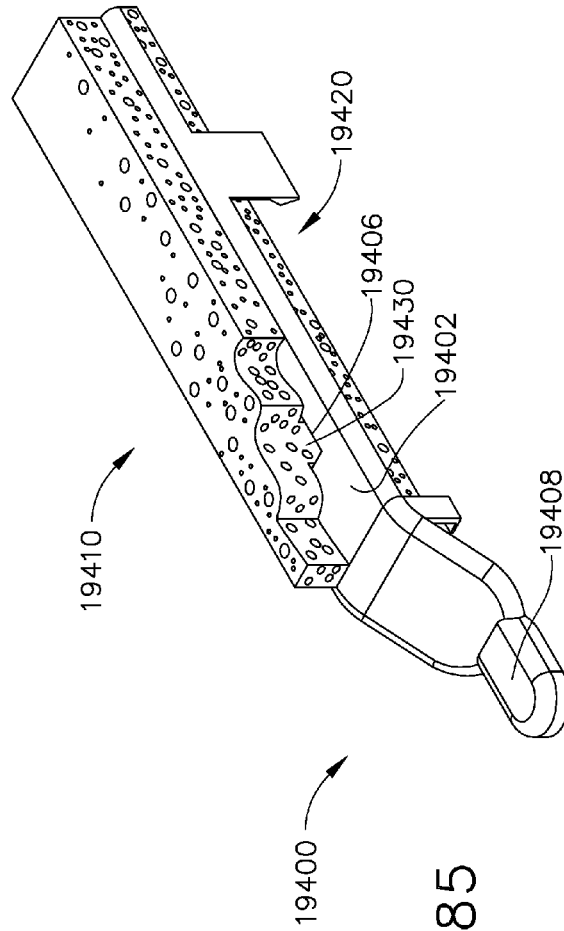
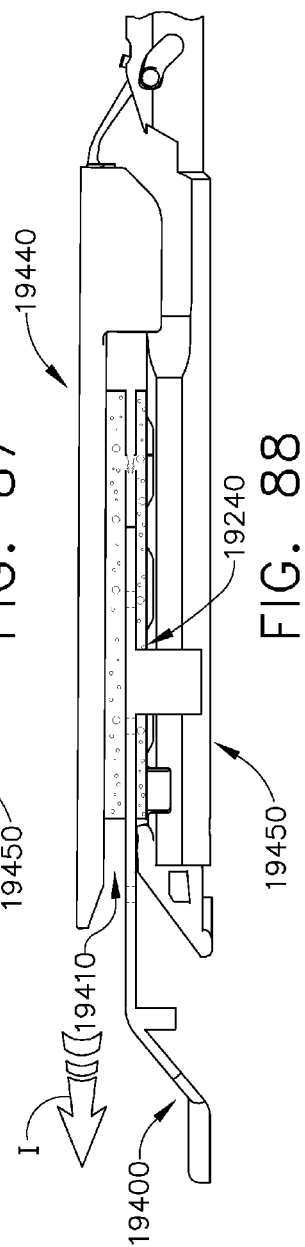
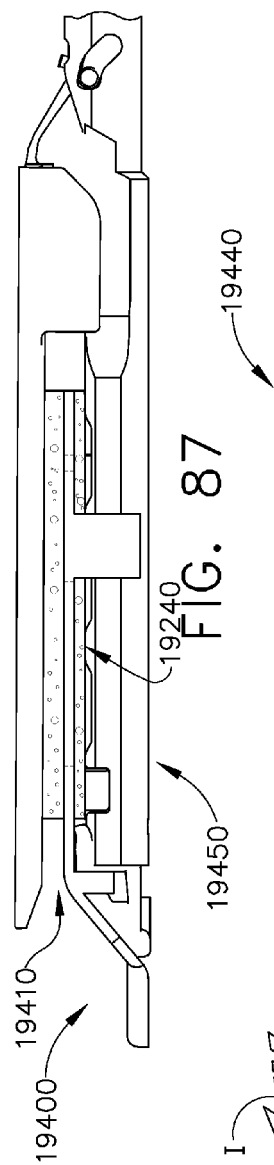
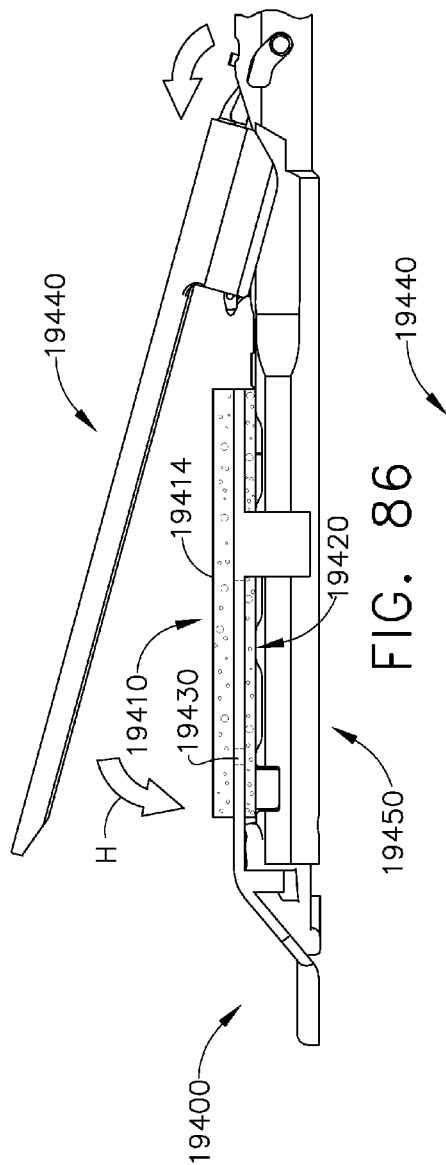


FIG. 85



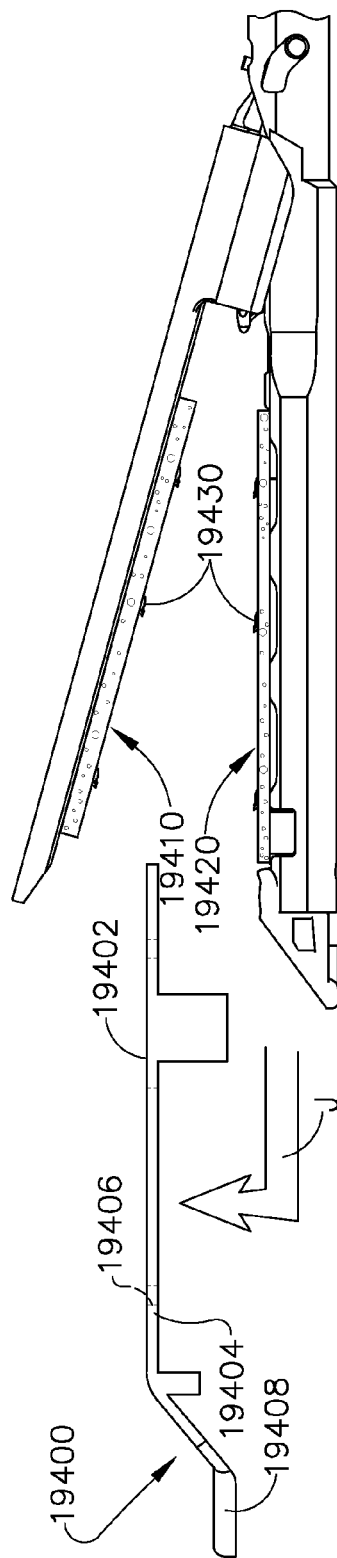


FIG. 89



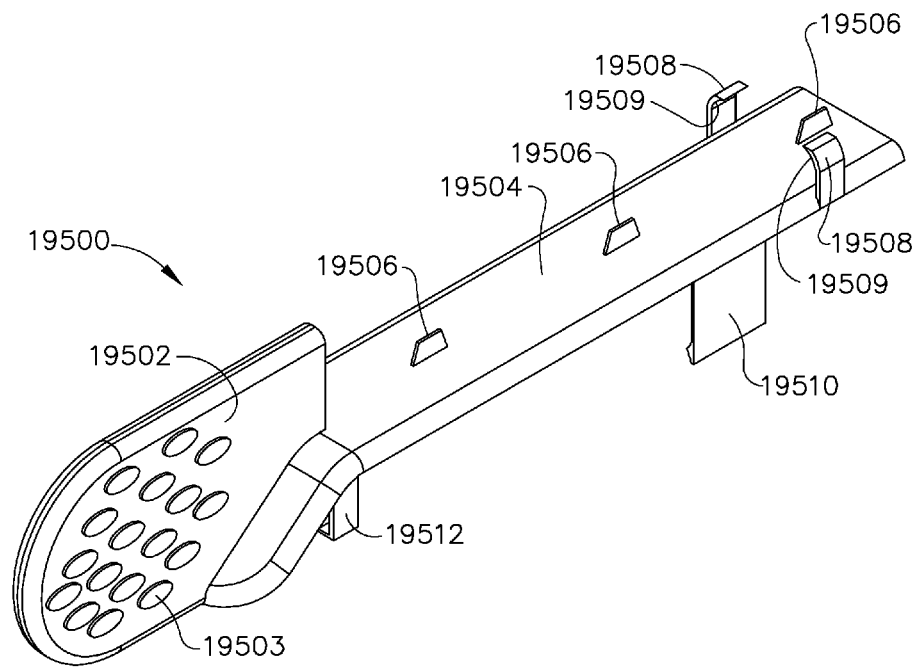


FIG. 90

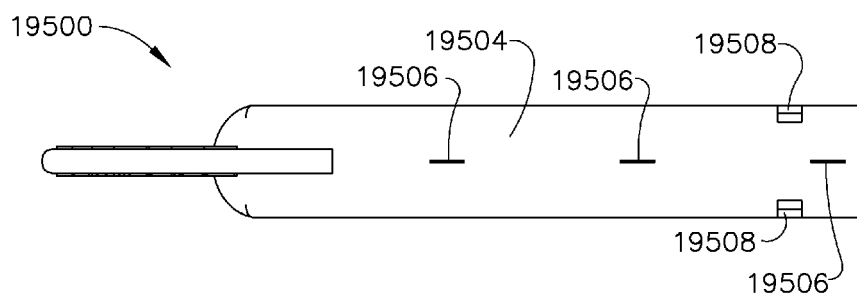


FIG. 91

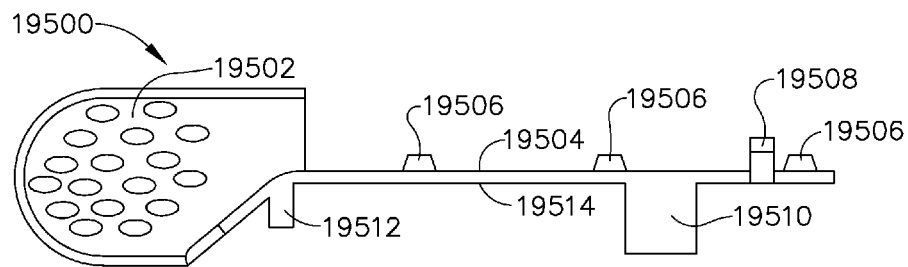


FIG. 92

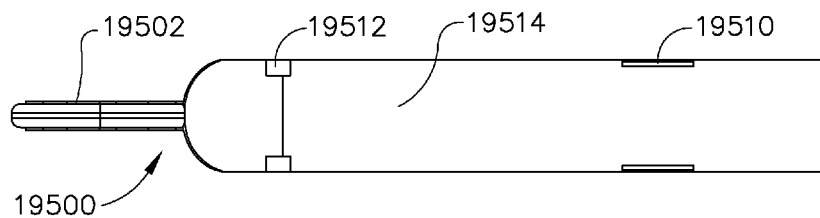


FIG. 93

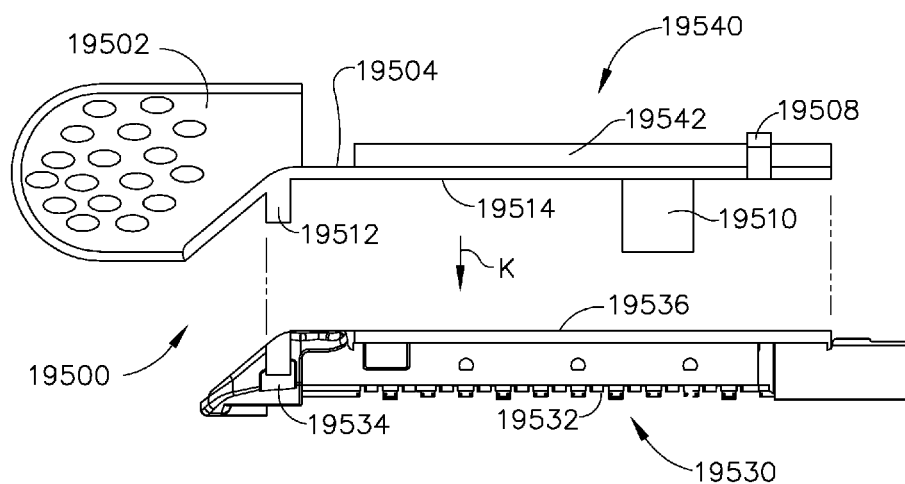


FIG. 94

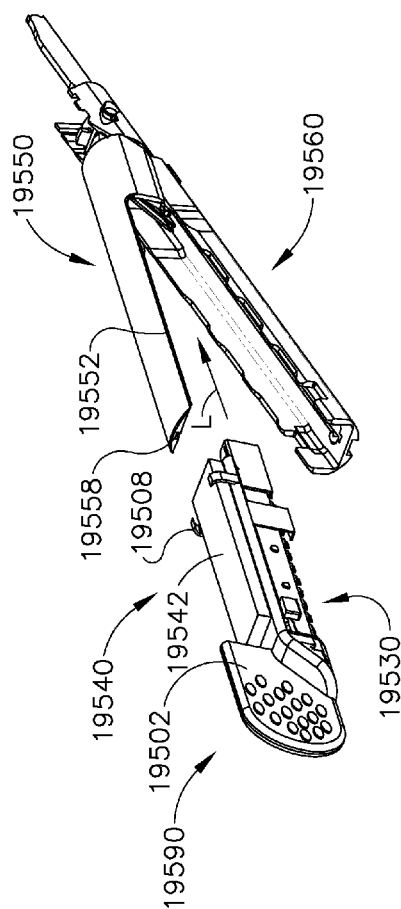


FIG. 95

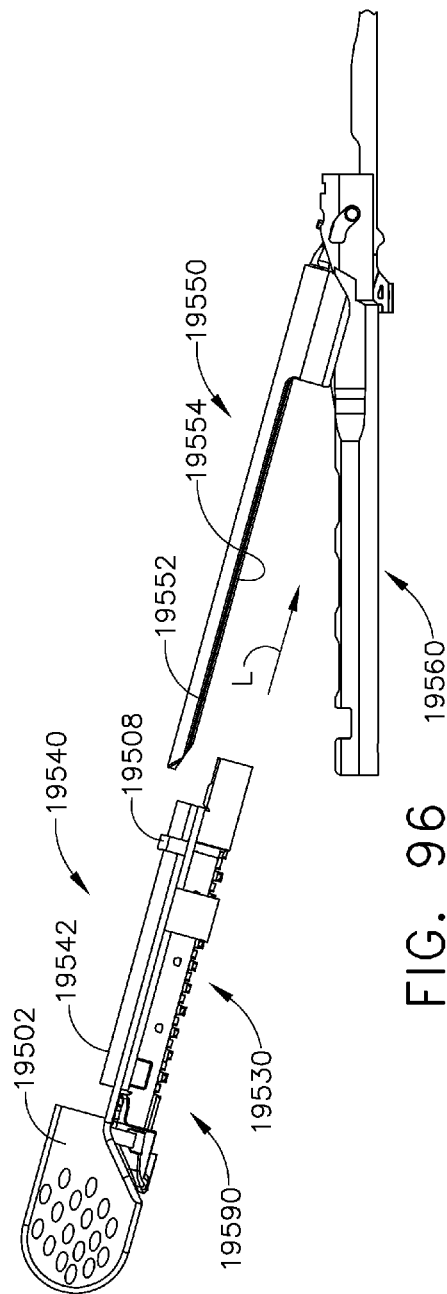


FIG. 96

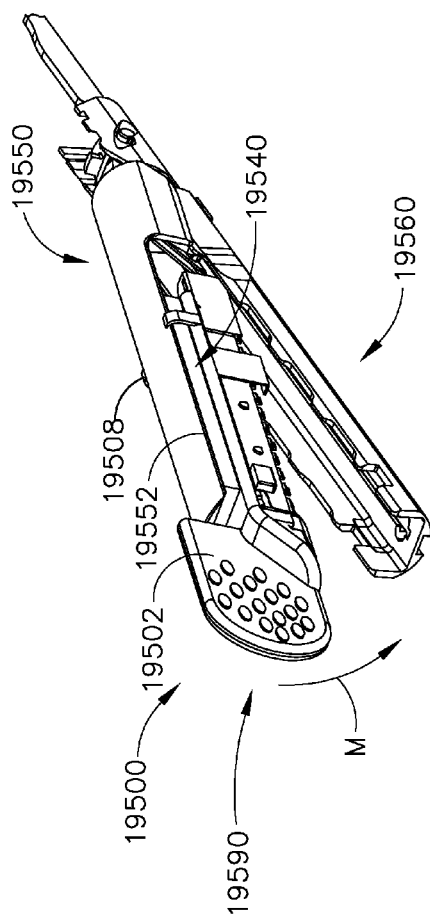


FIG. 97

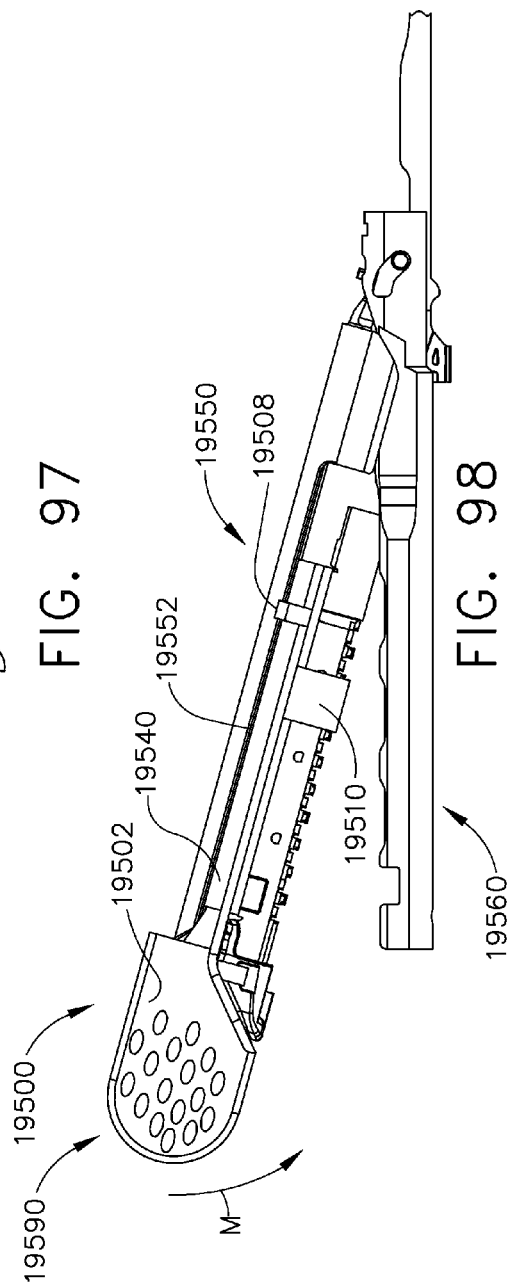
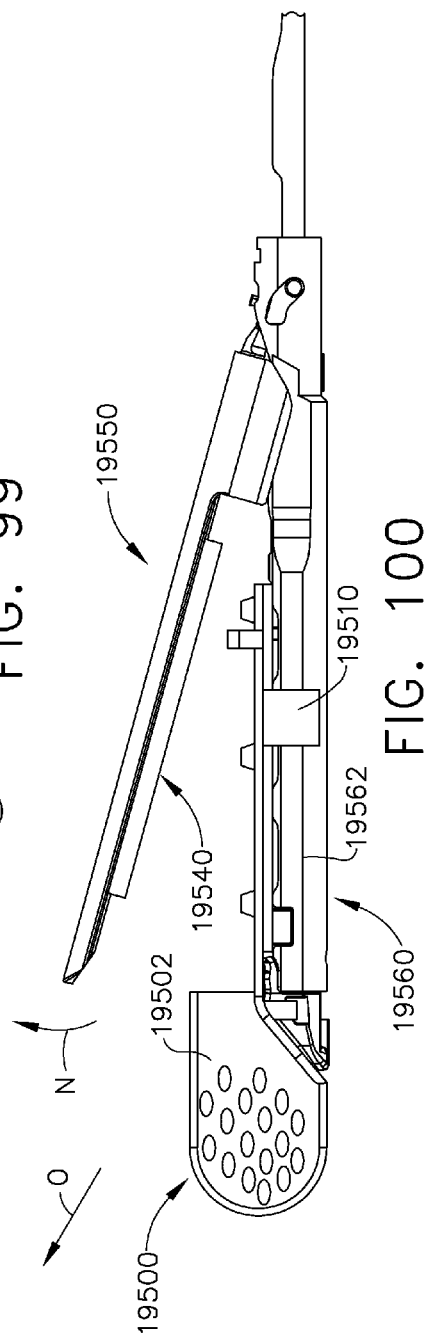
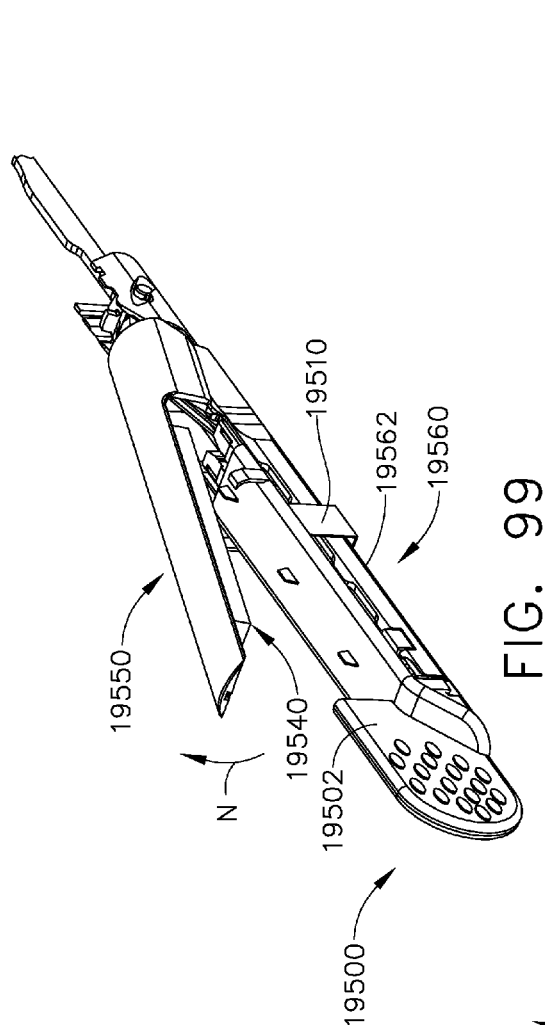


FIG. 98



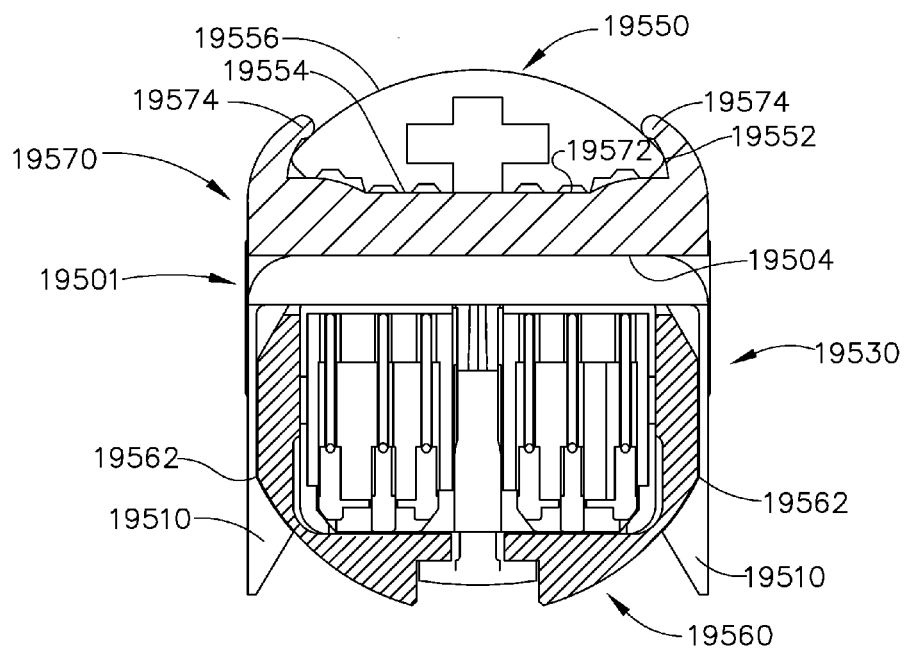


FIG. 101

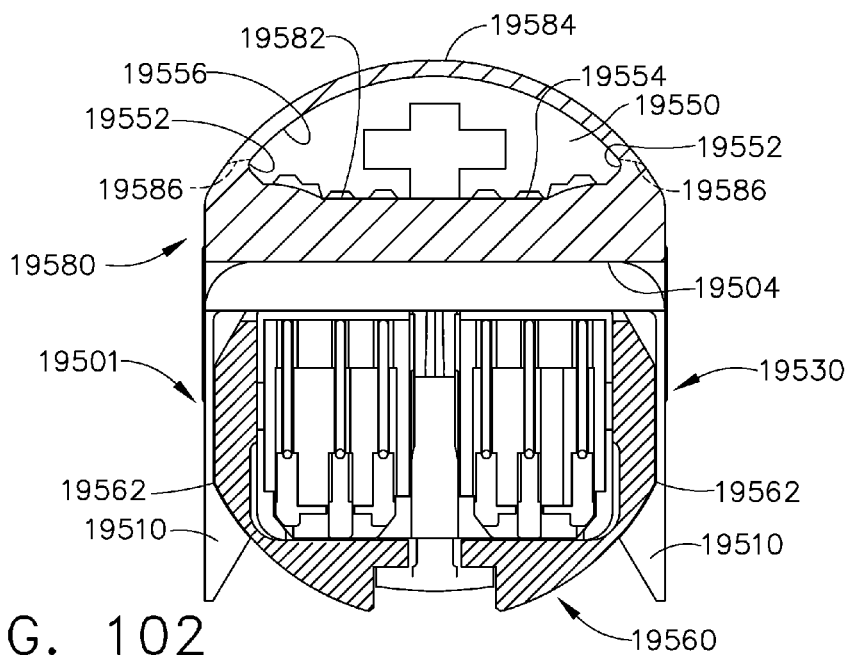
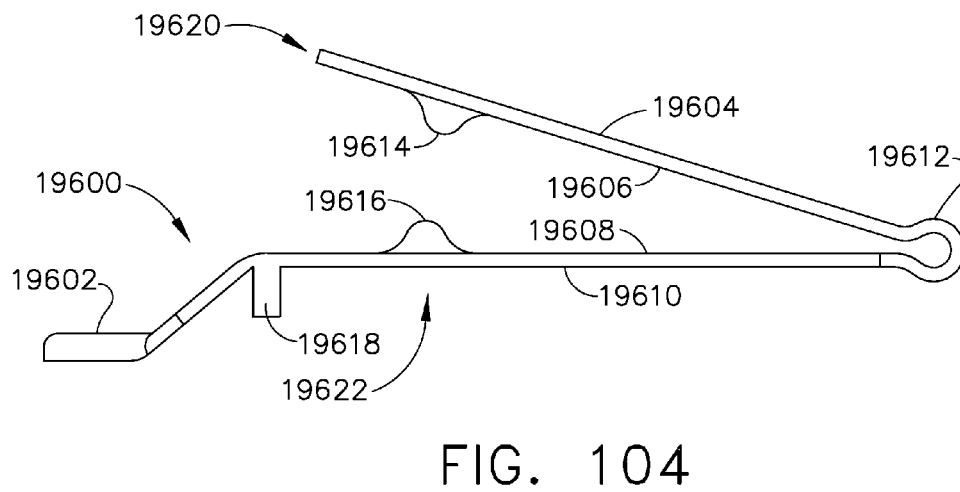
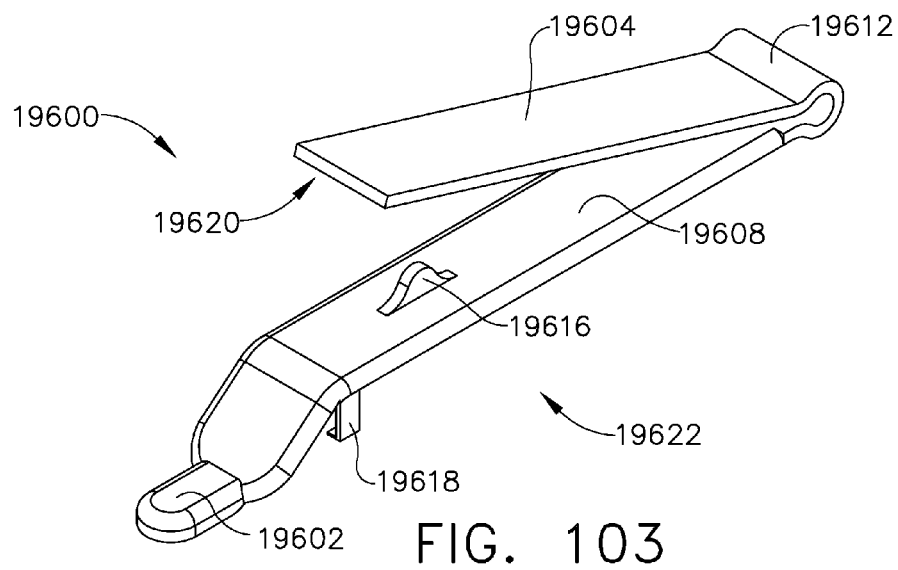


FIG. 102



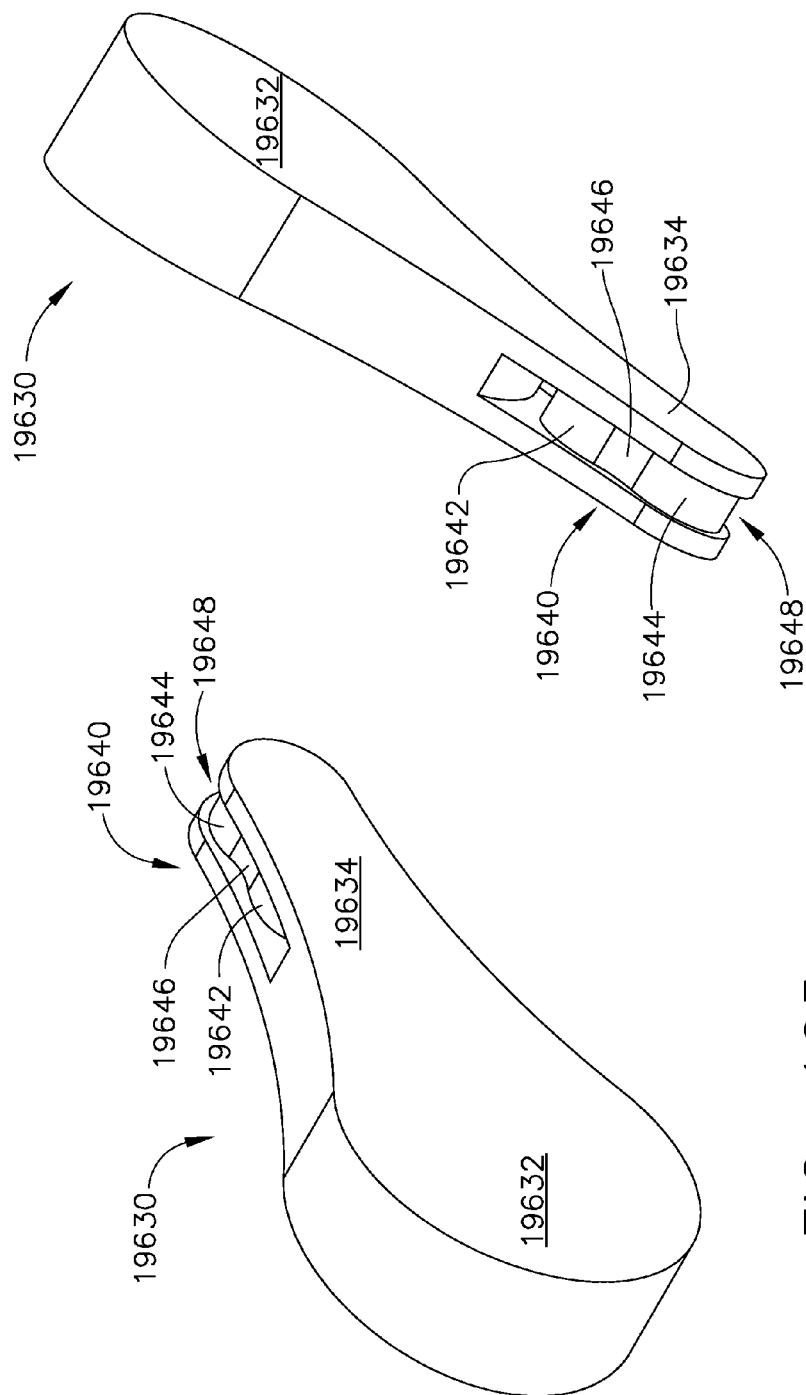


FIG. 106

FIG. 105



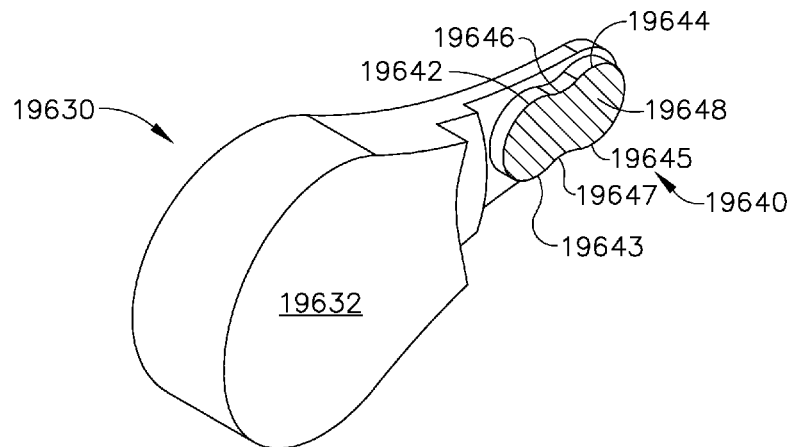


FIG. 107

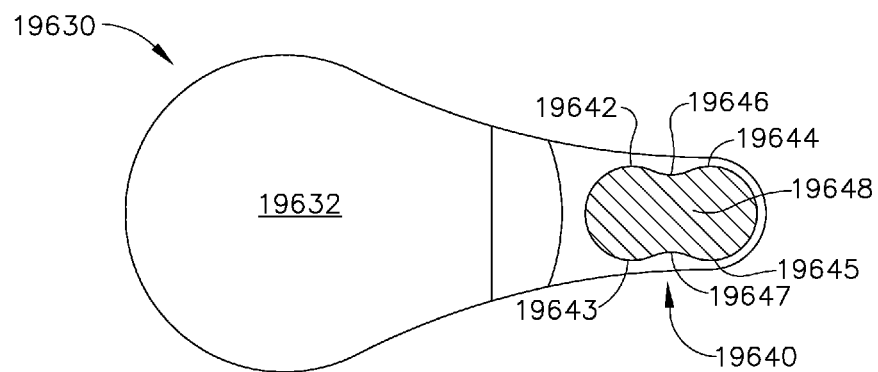


FIG. 108

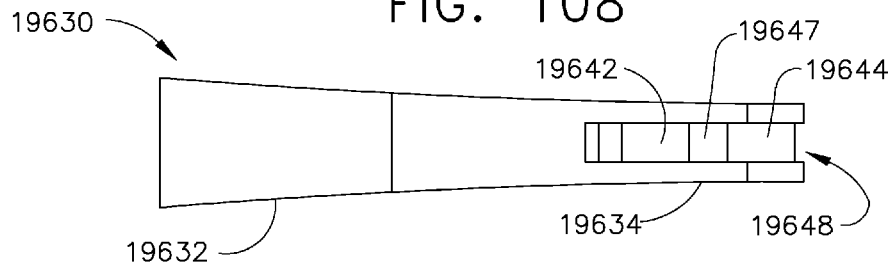


FIG. 109

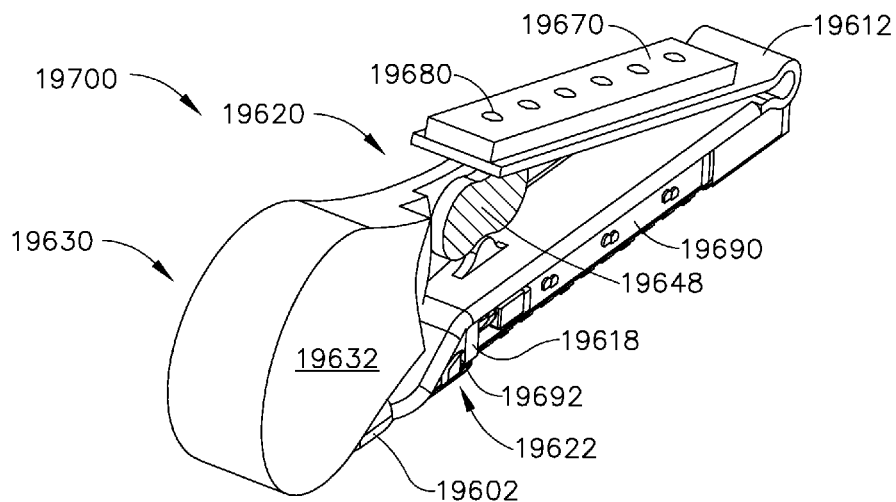


FIG. 110

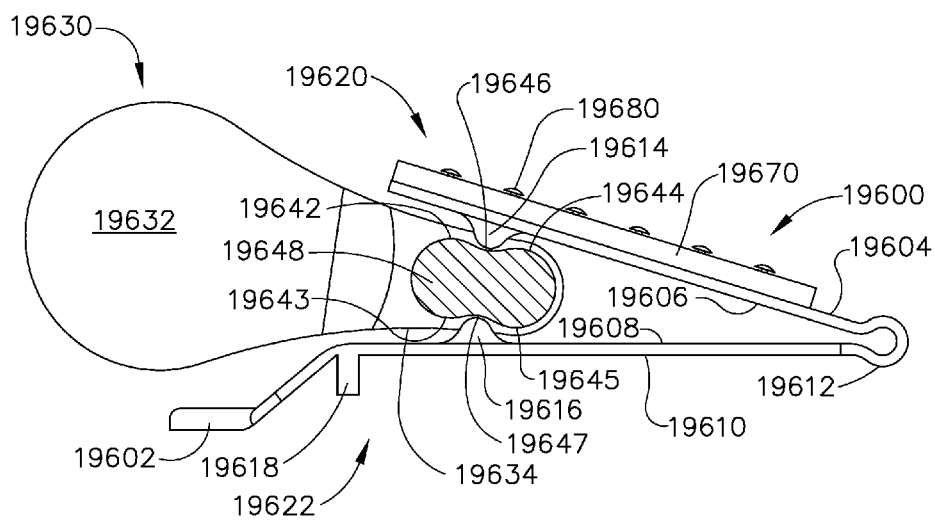


FIG. 111

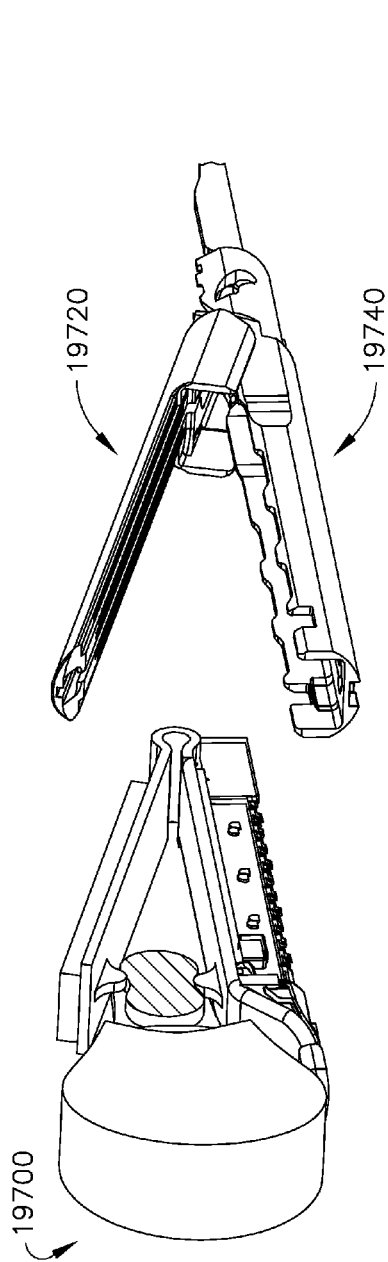


FIG. 112

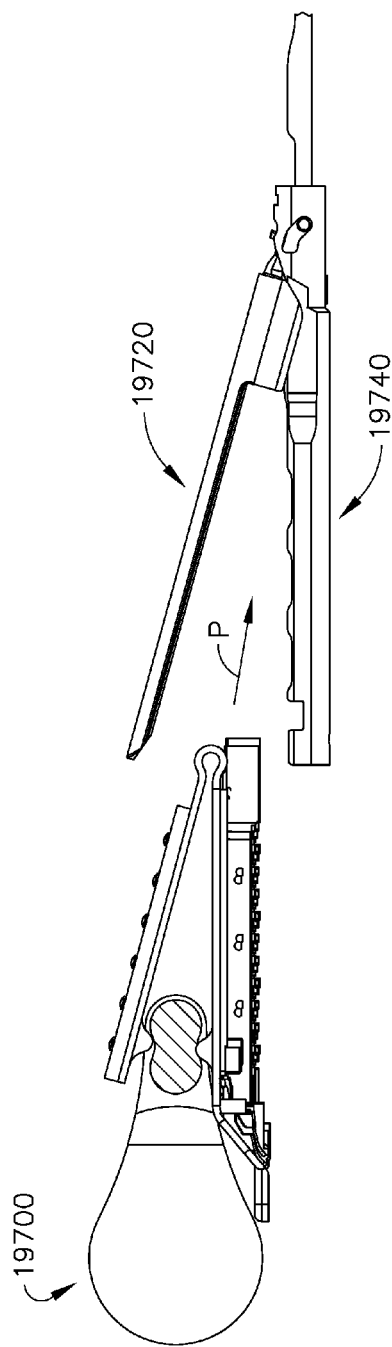
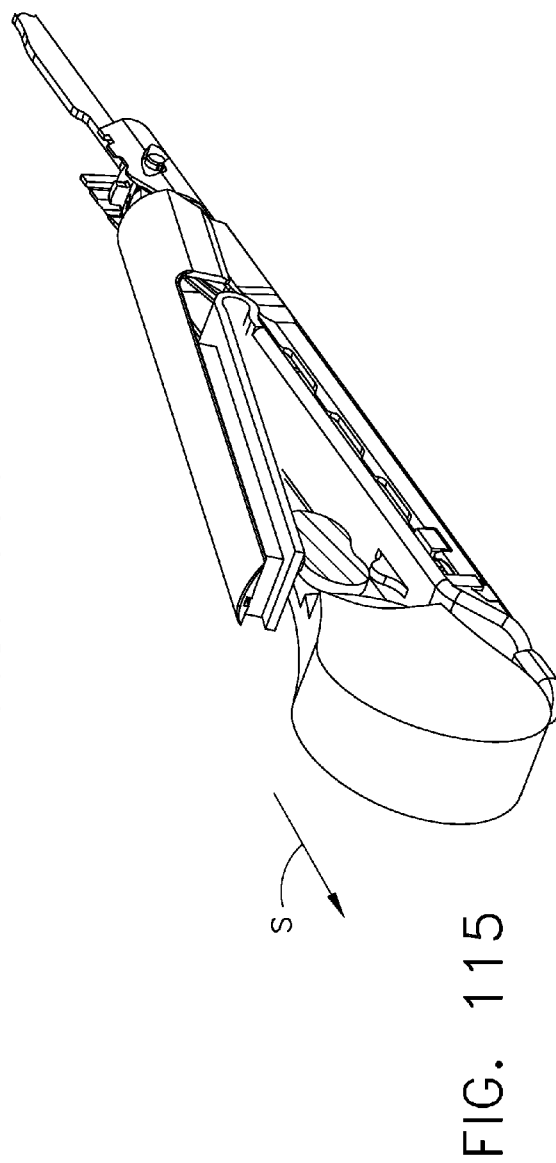
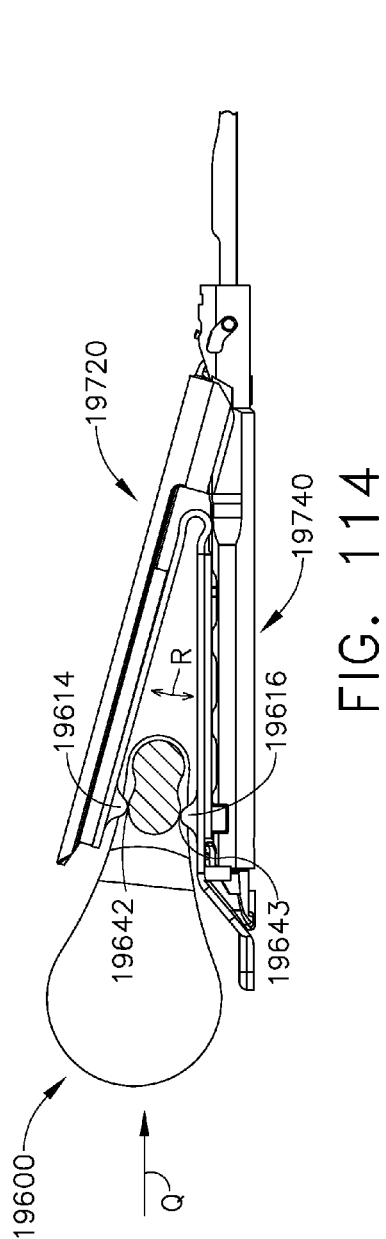


FIG. 113



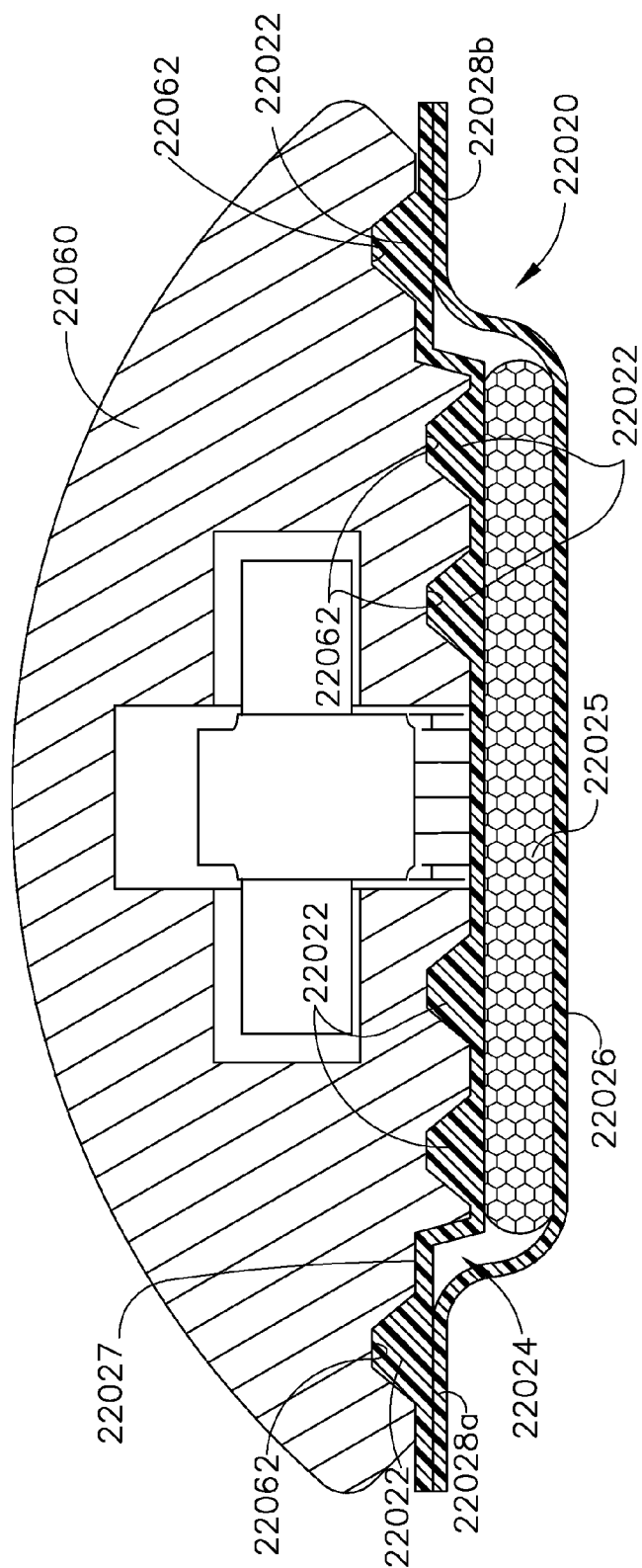


FIG. 116

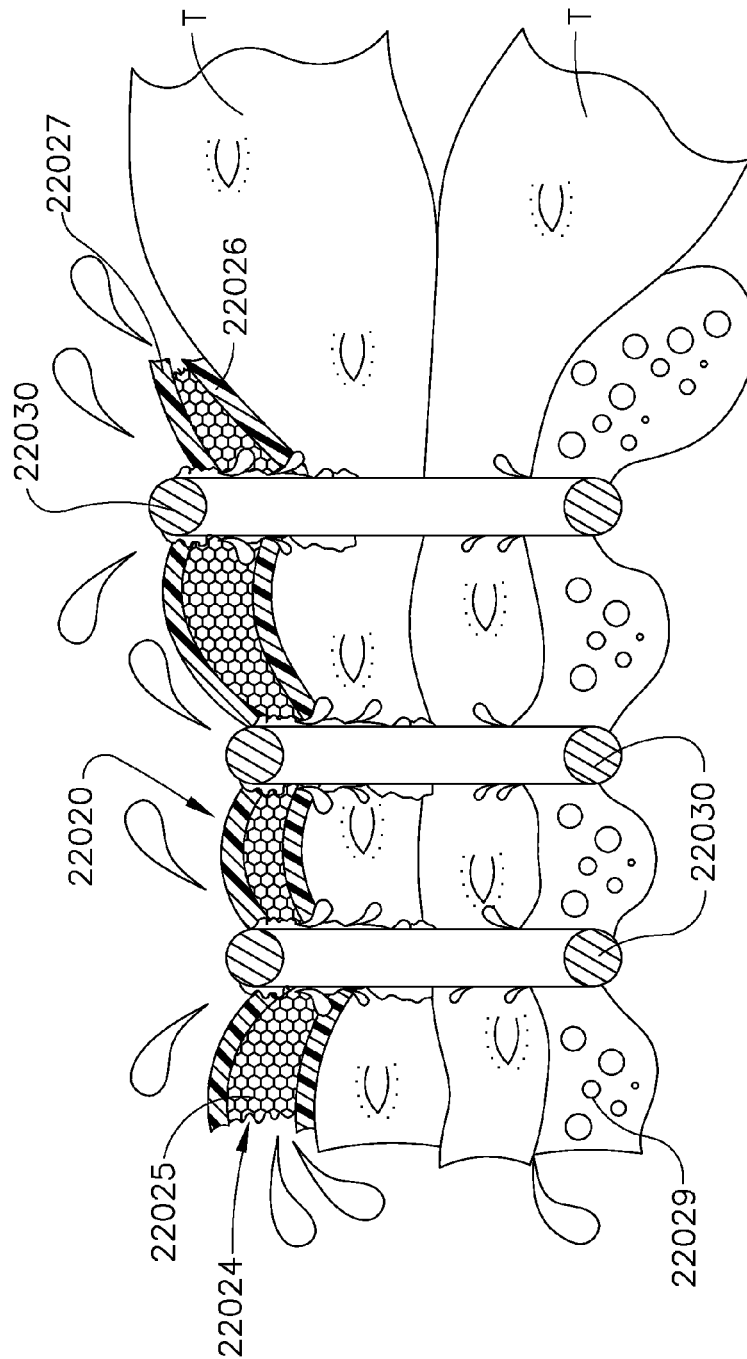


FIG. 117

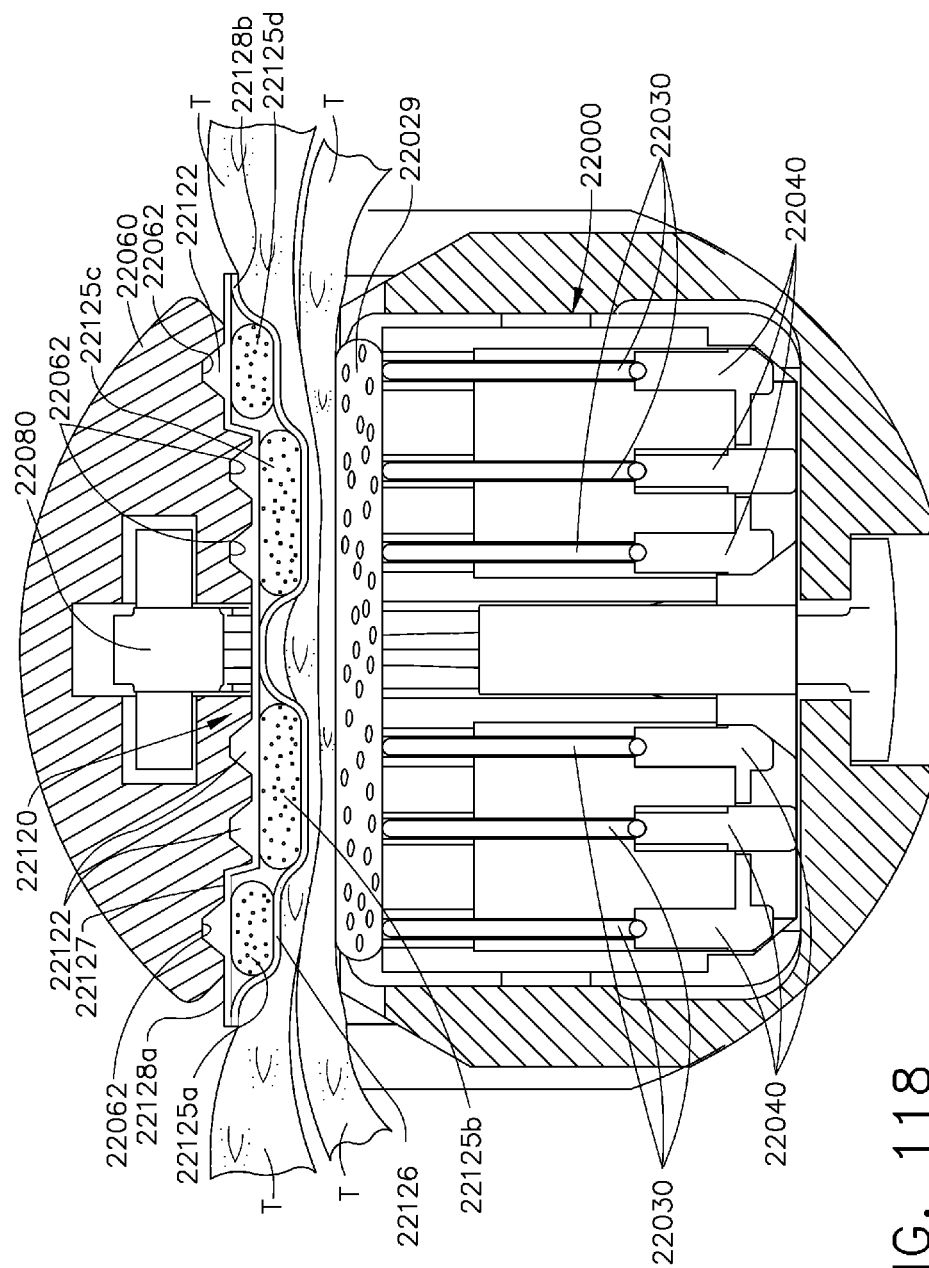


FIG. 118

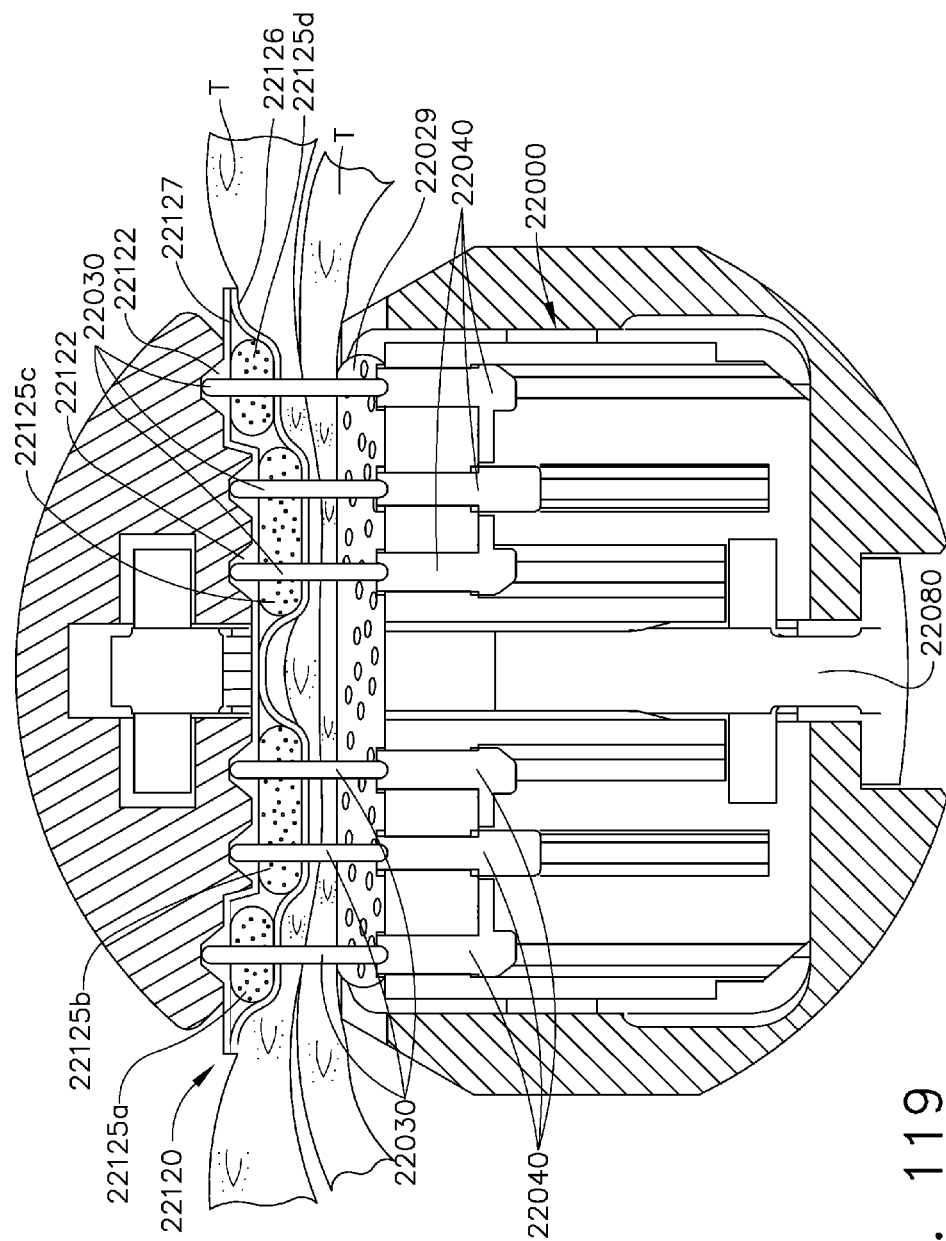


FIG. 119



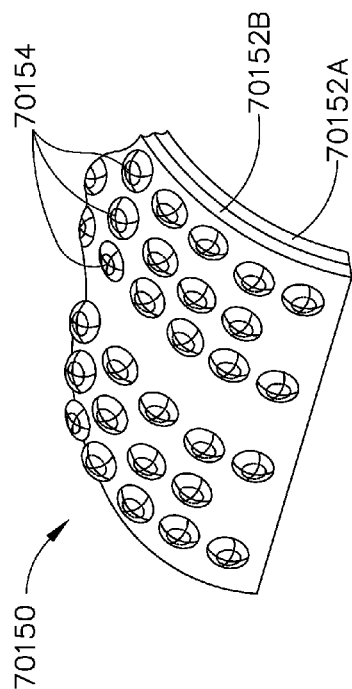


FIG. 120A

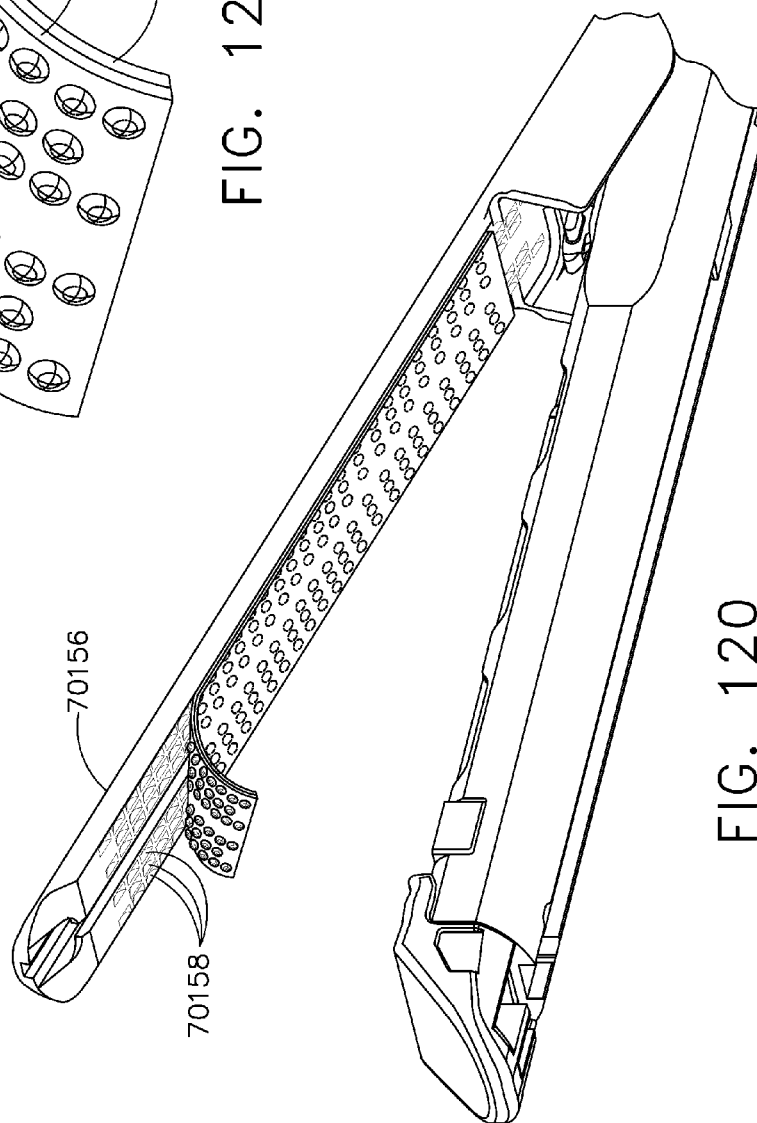


FIG. 120

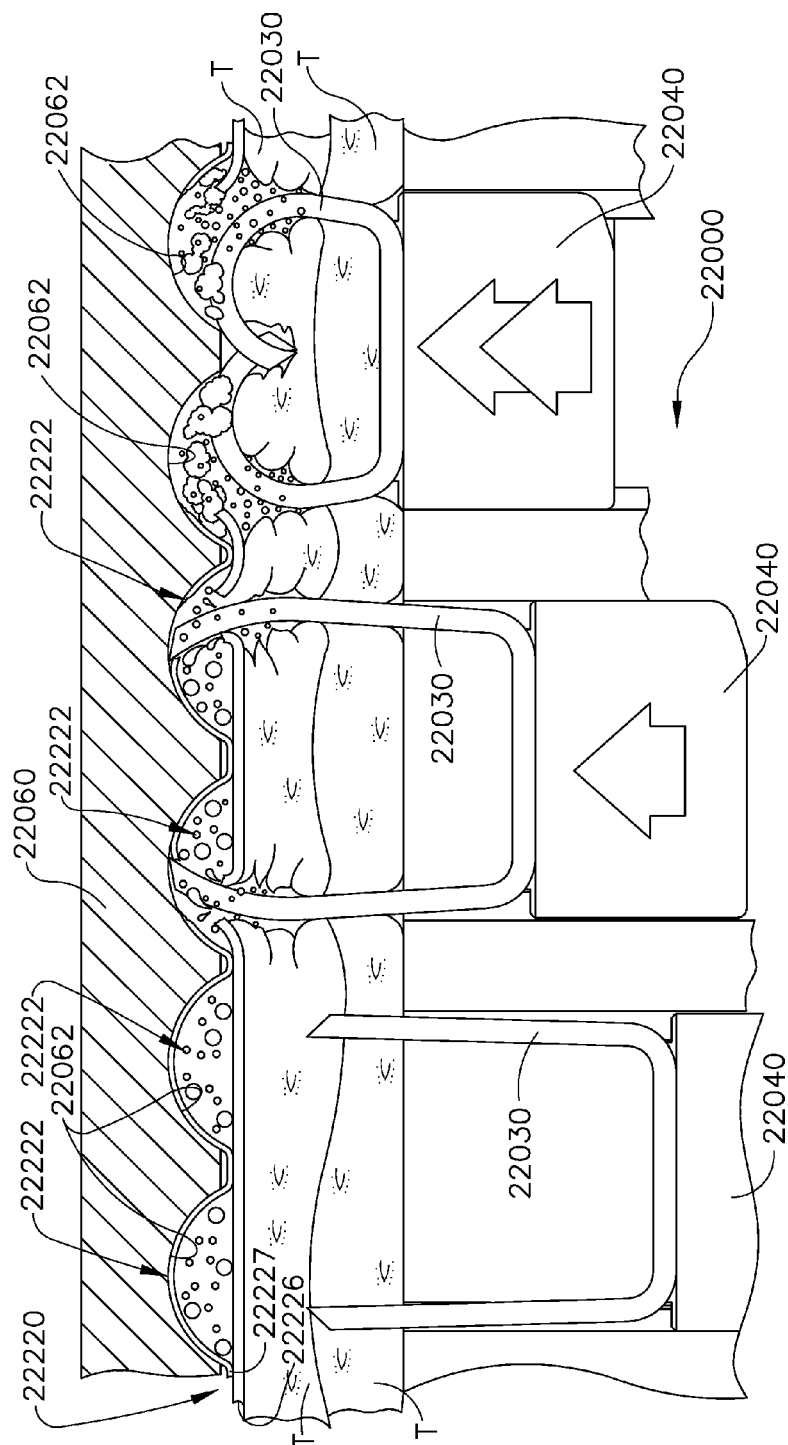


FIG. 121

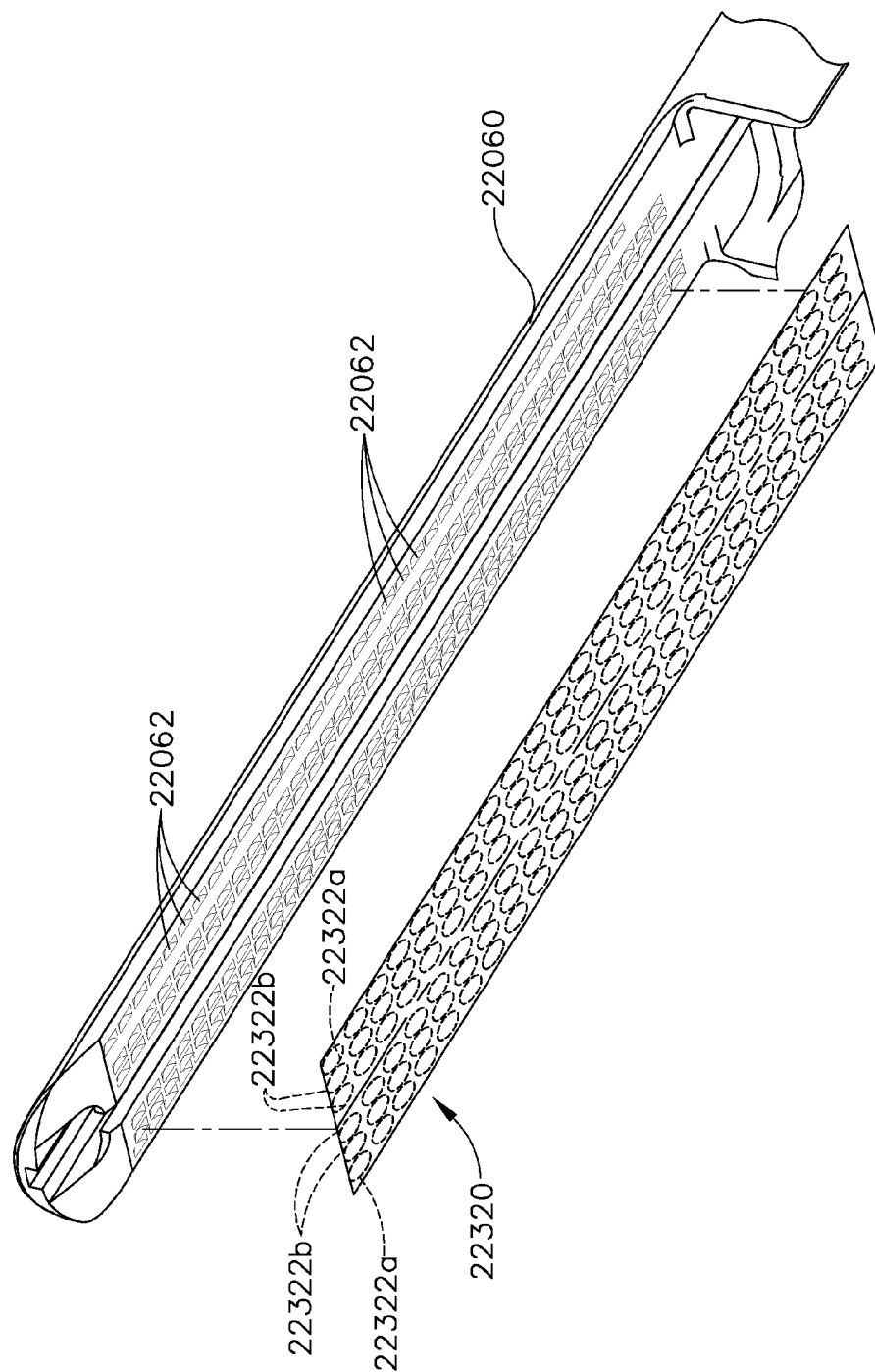


FIG. 122

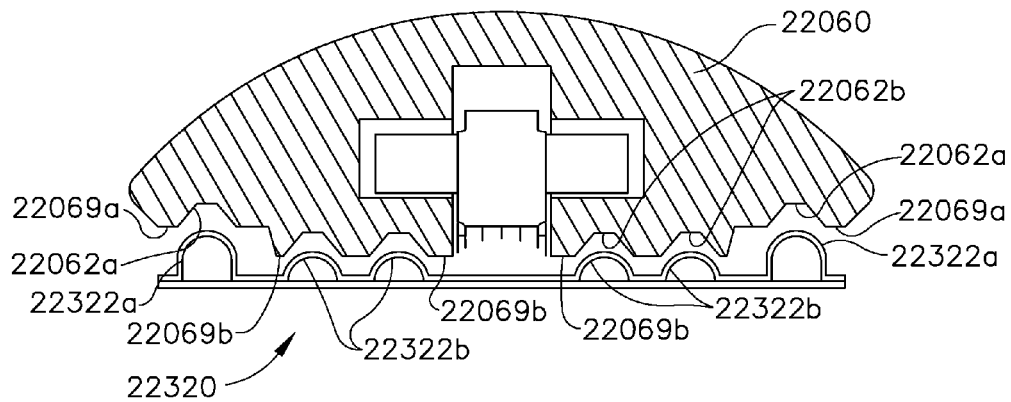


FIG. 123

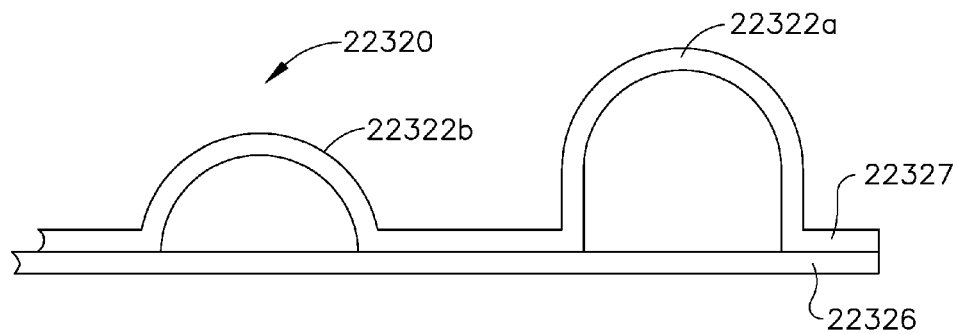


FIG. 124

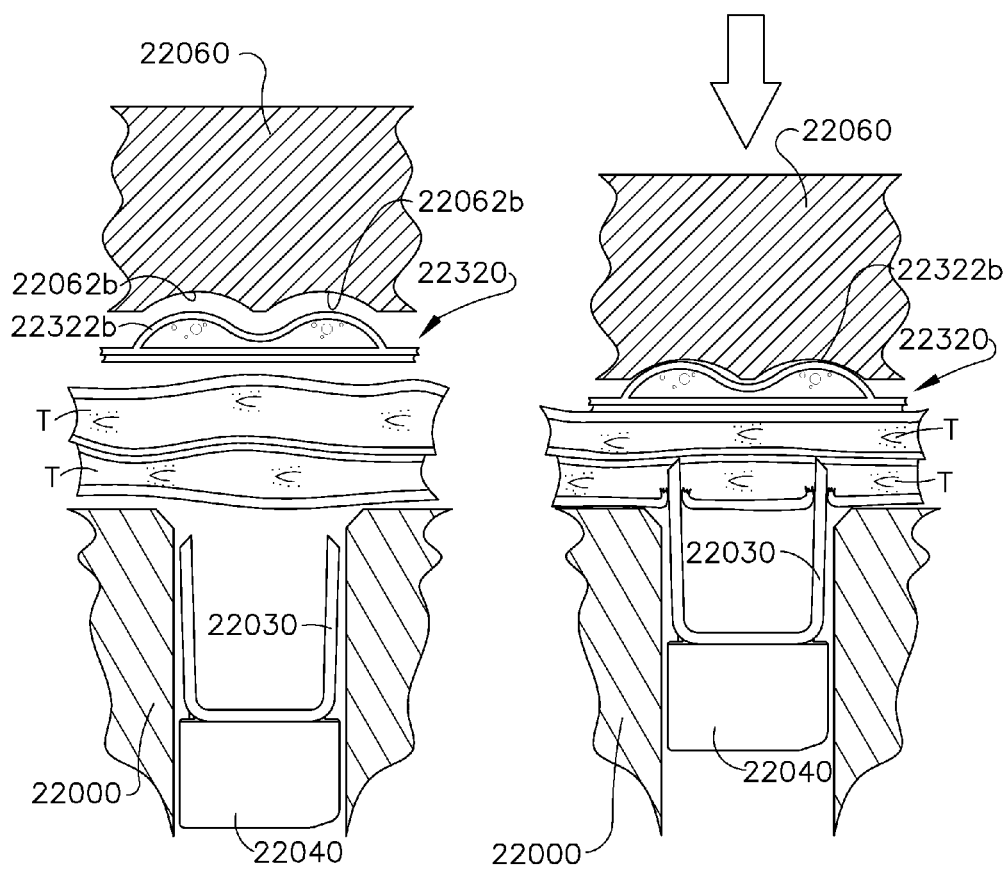


FIG. 125

FIG. 126

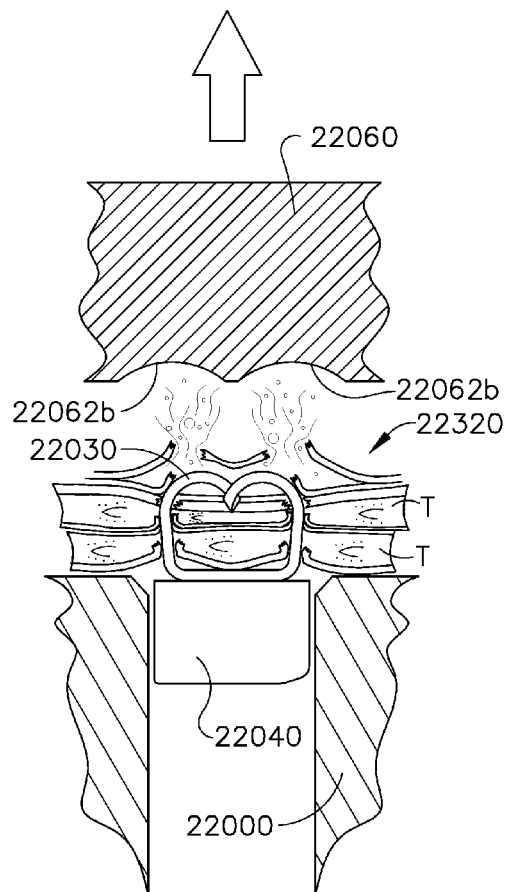


FIG. 127

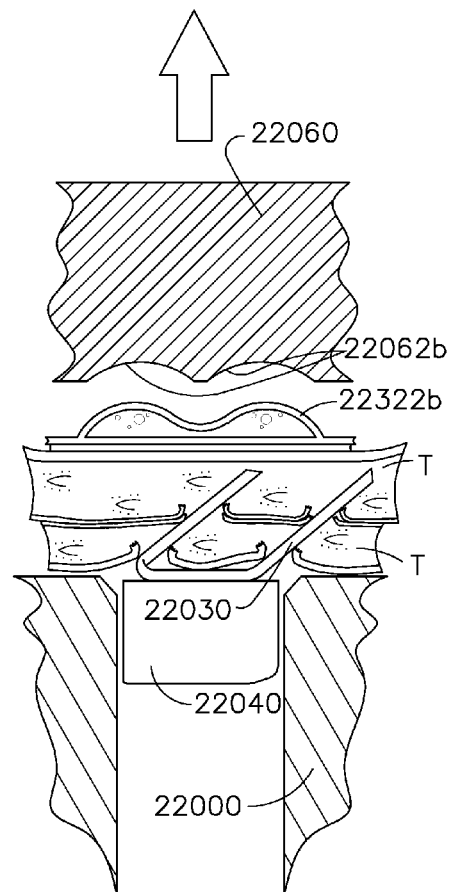


FIG. 128

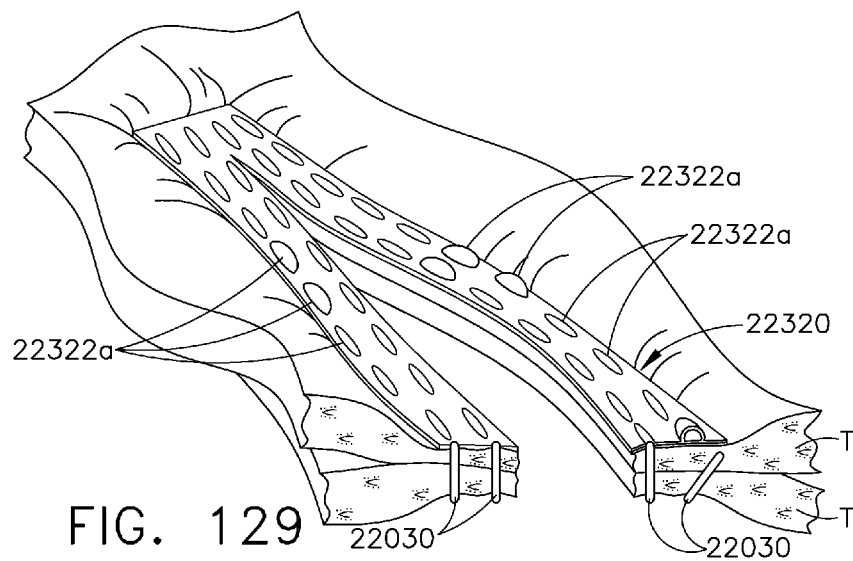


FIG. 129

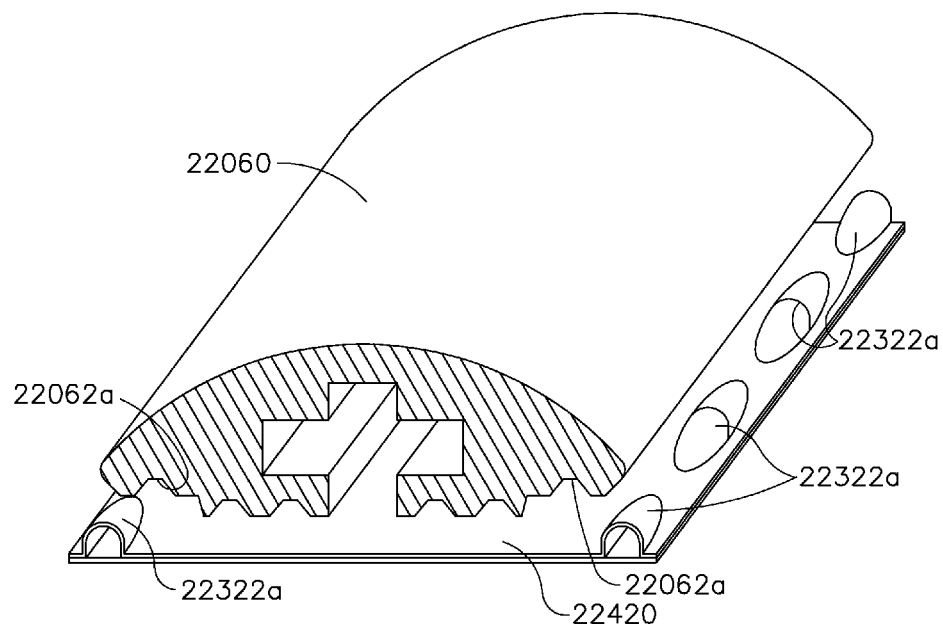


FIG. 130

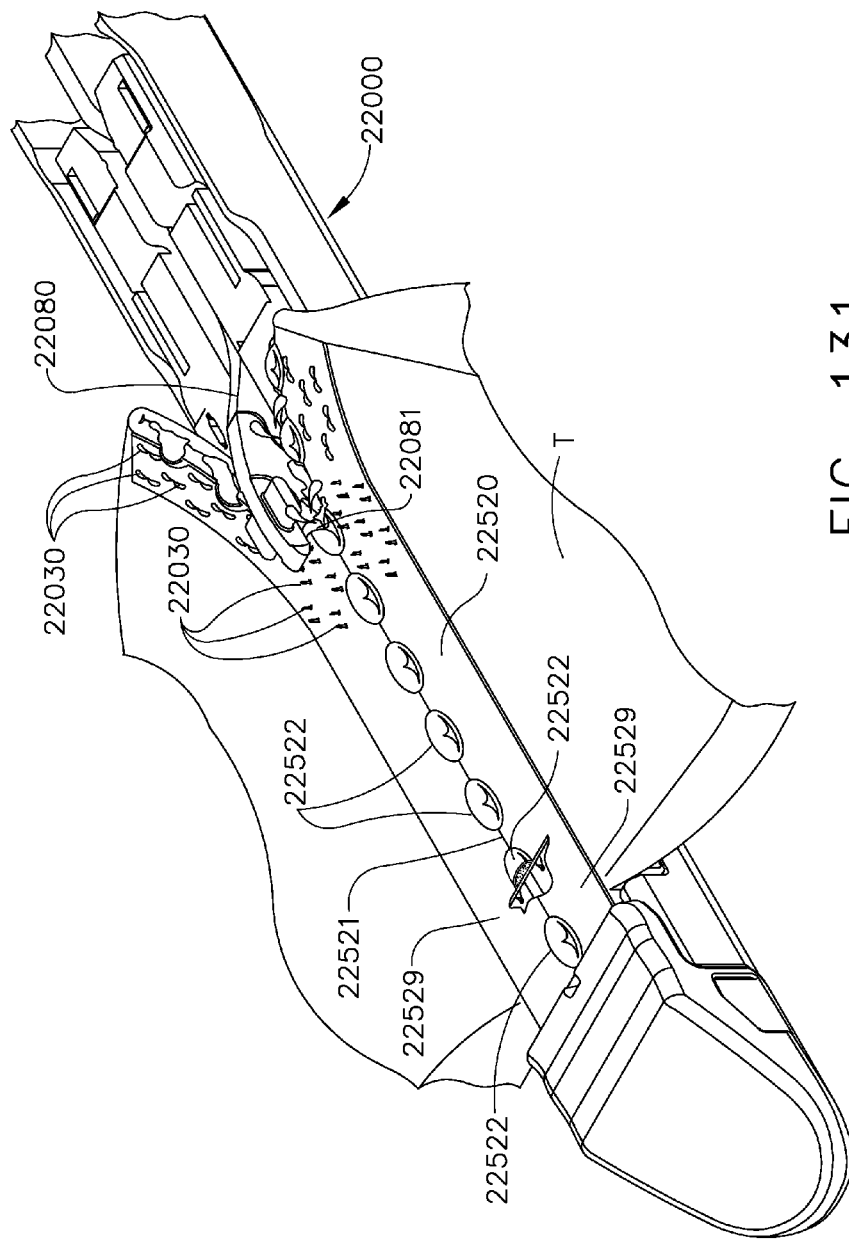
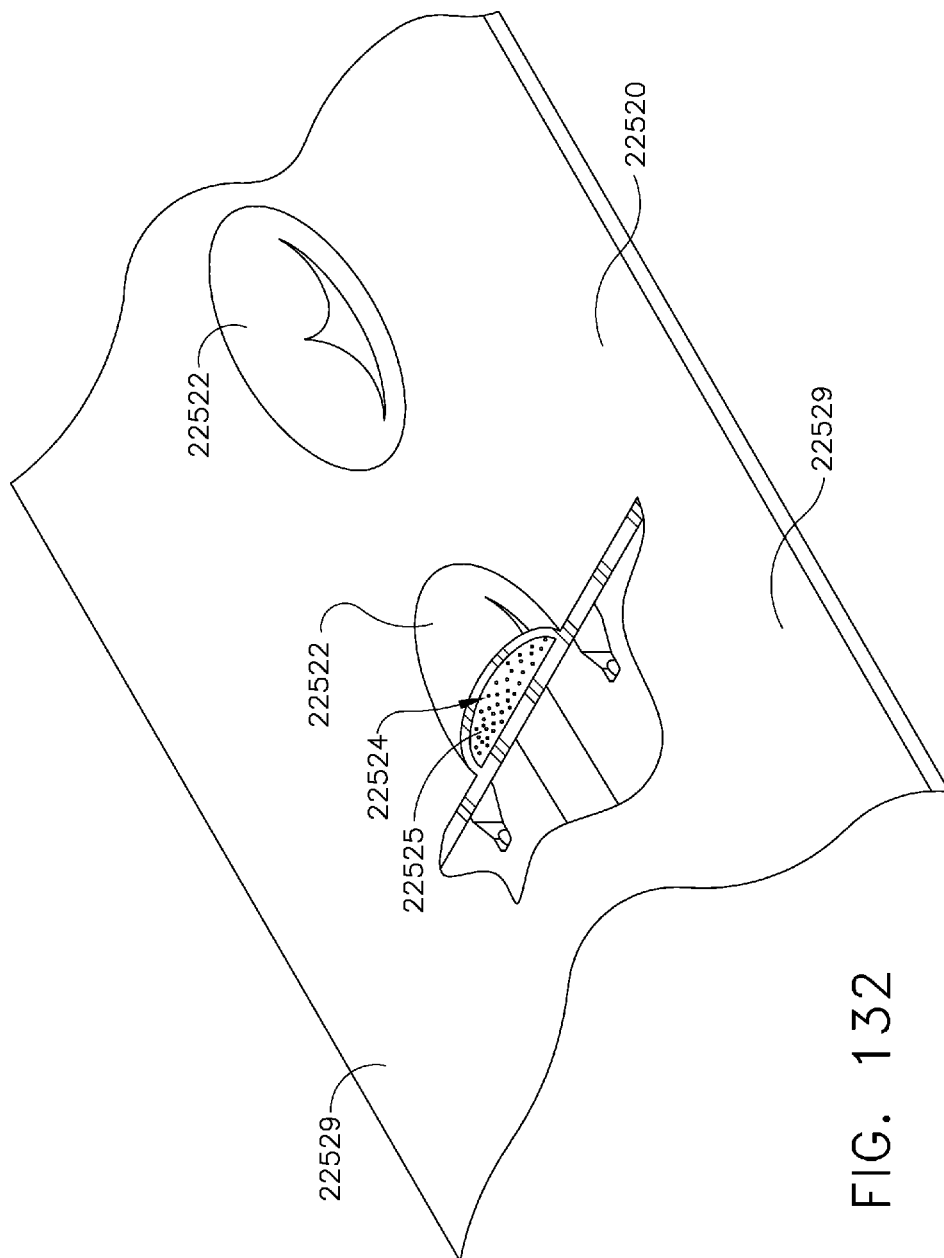


FIG. 131





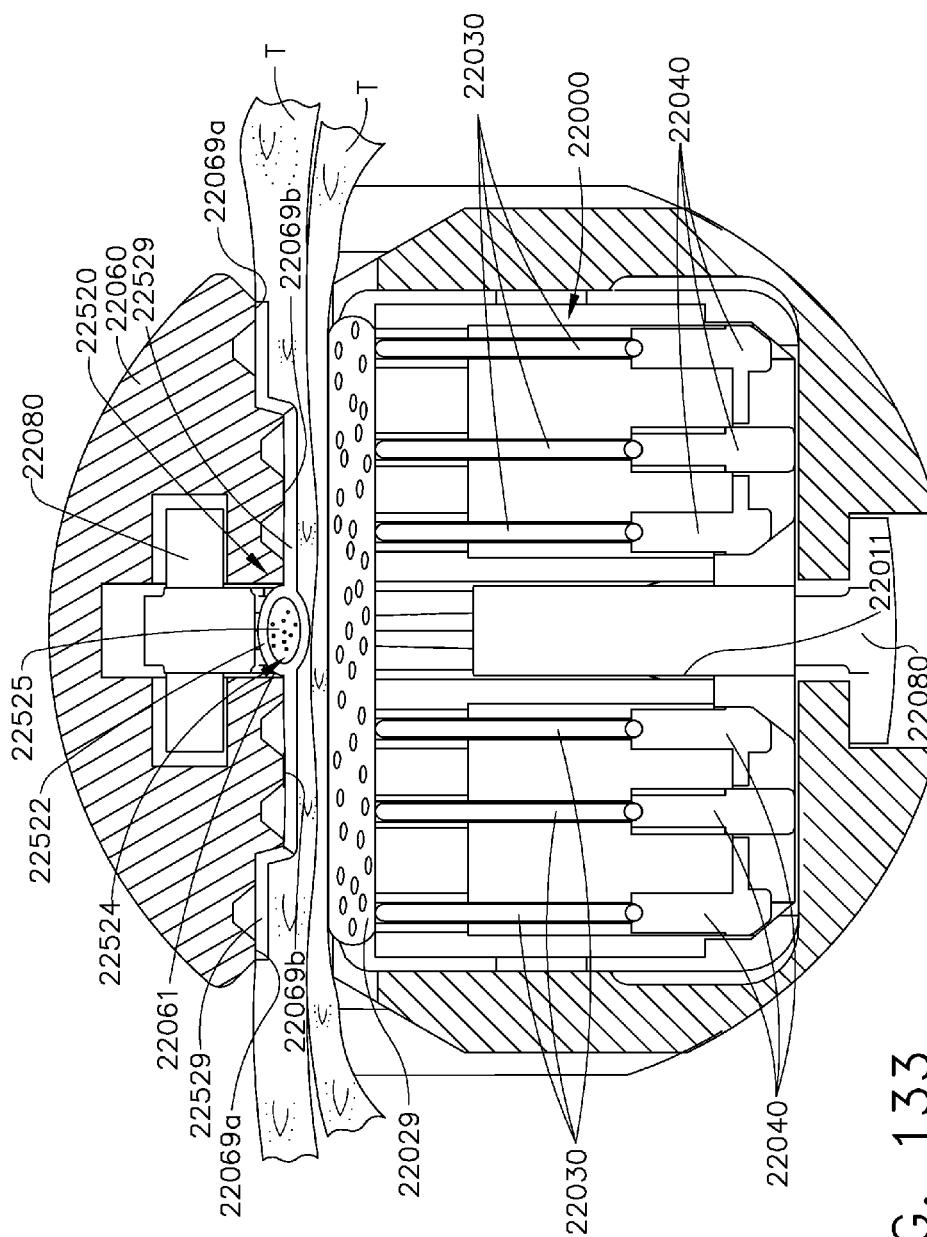
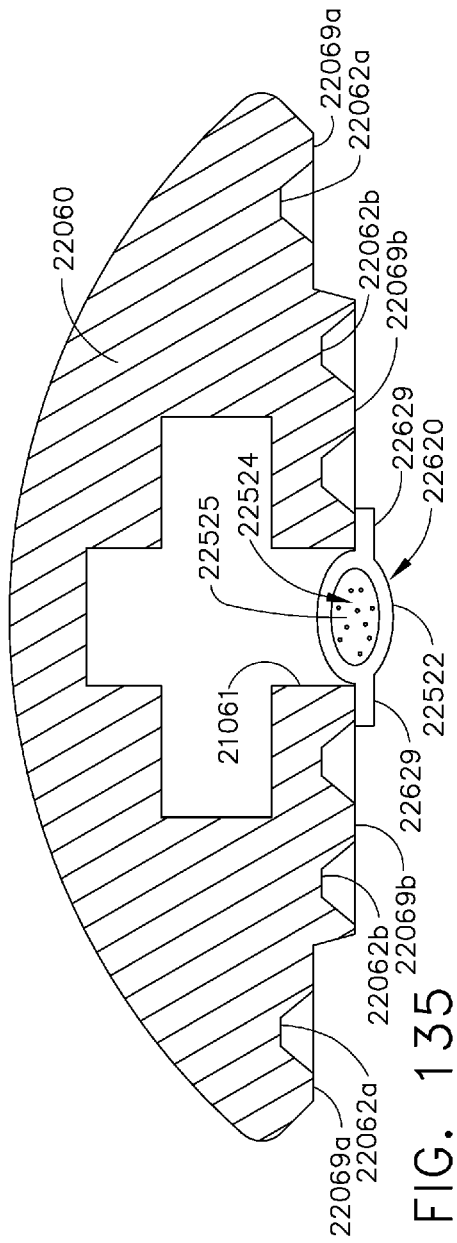
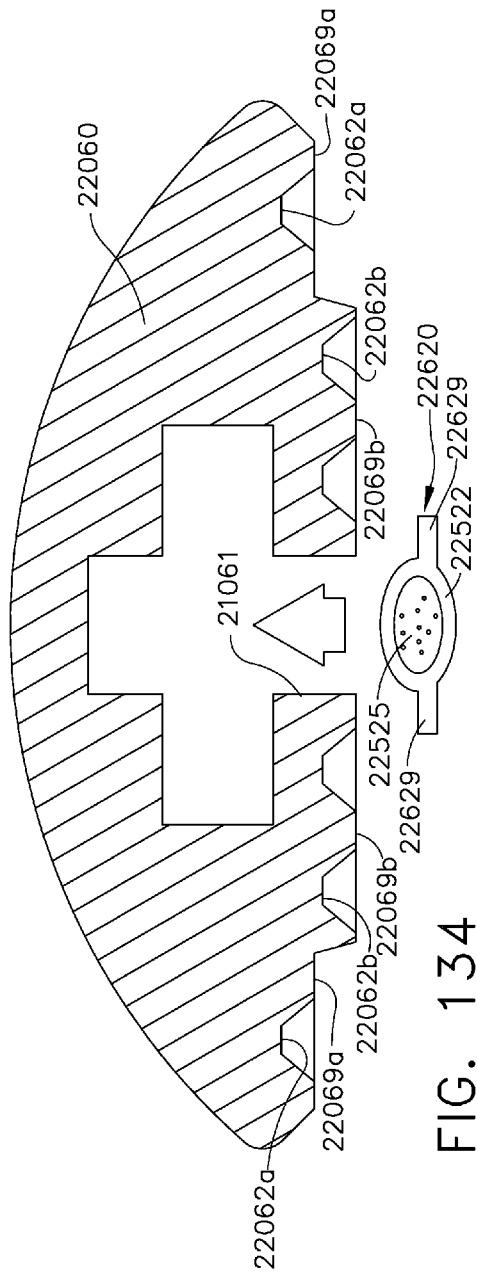


FIG. 133



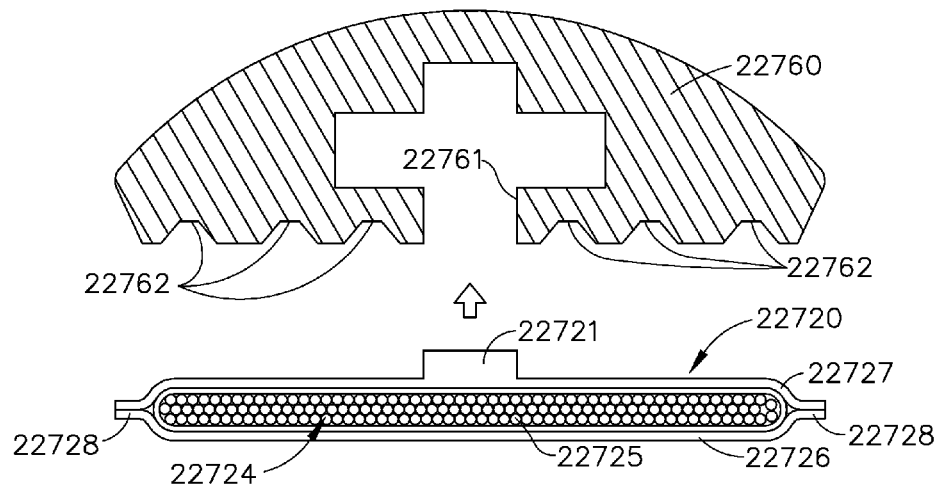


FIG. 136

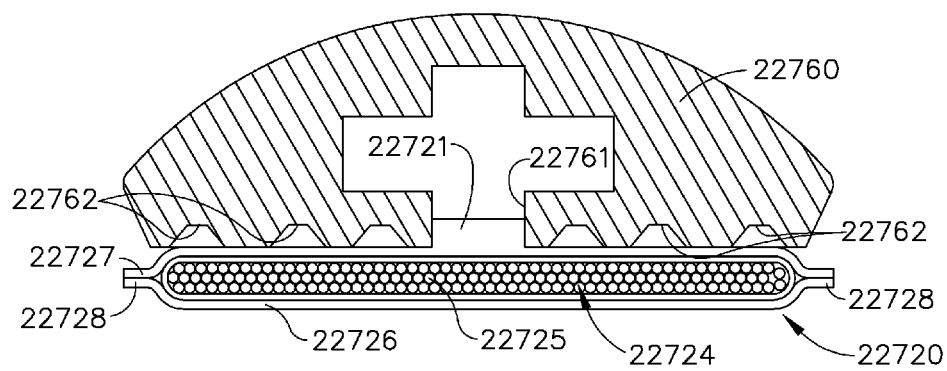


FIG. 137

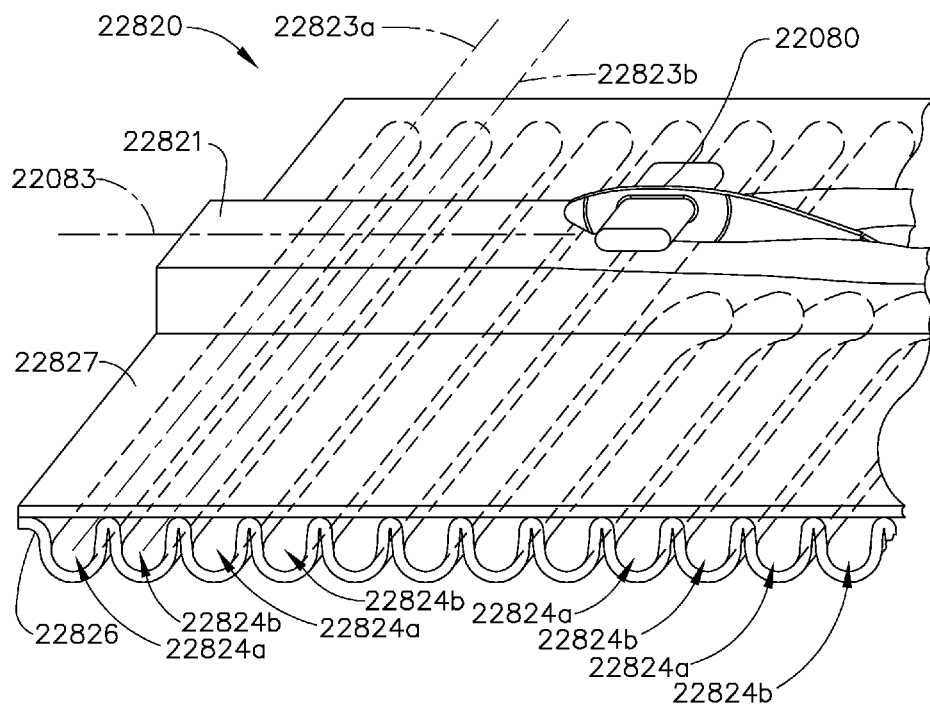


FIG. 138

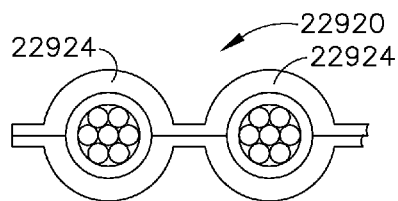


FIG. 139

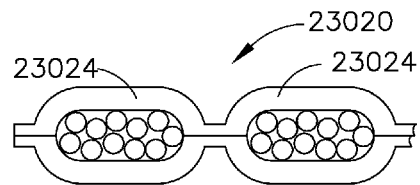


FIG. 140



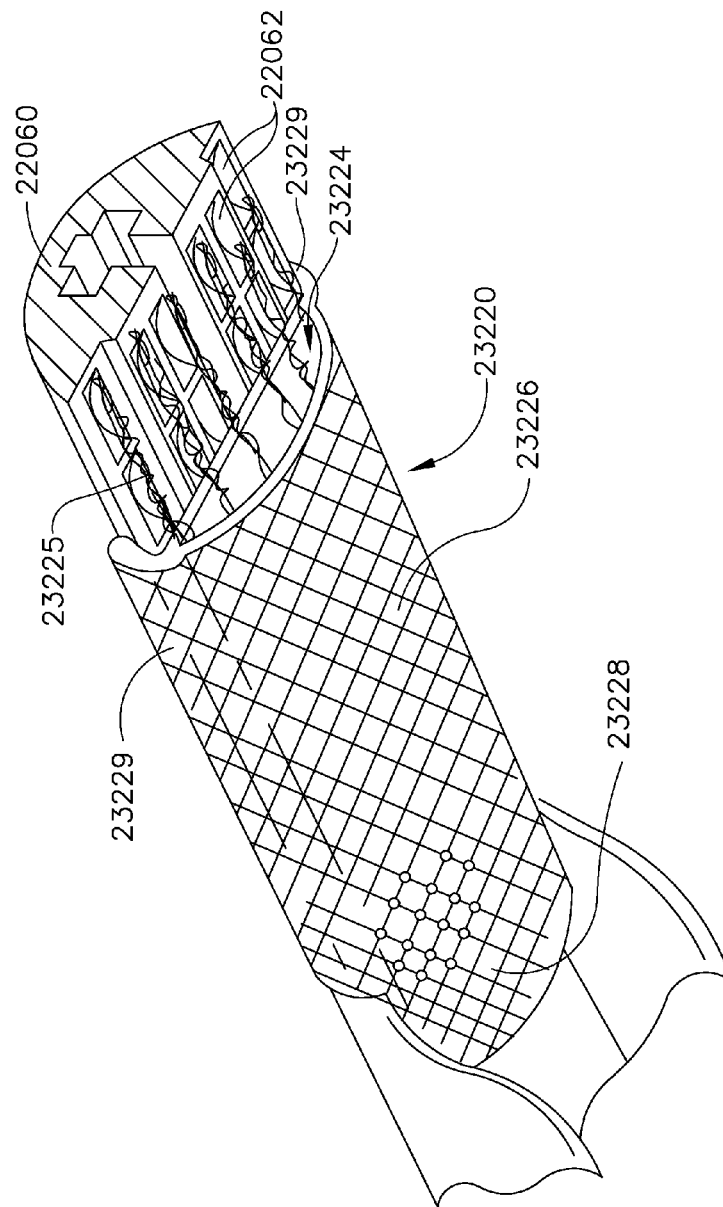


FIG. 142

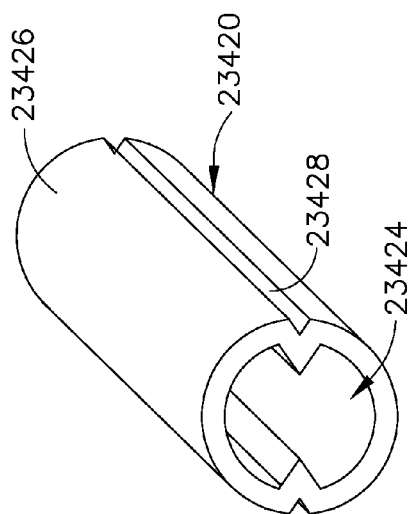


FIG. 144

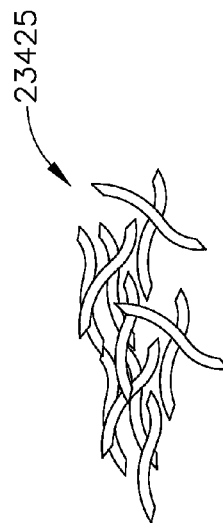


FIG. 146

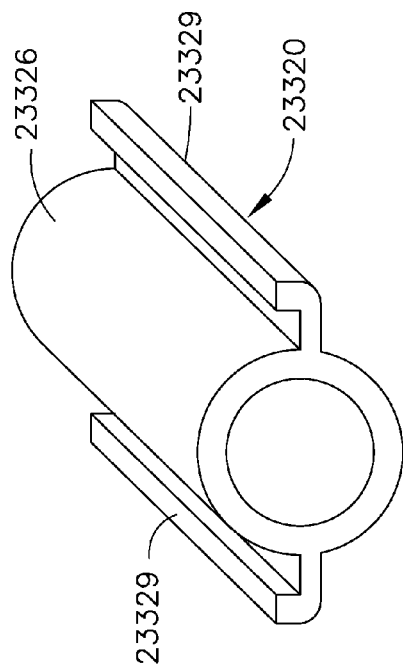


FIG. 143

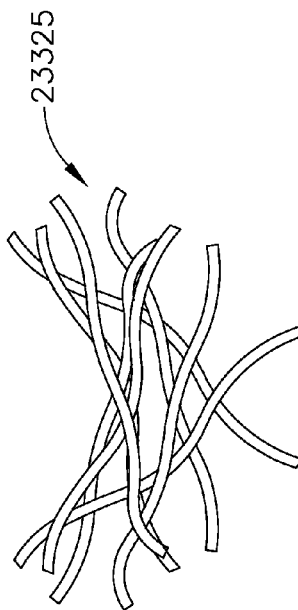


FIG. 145



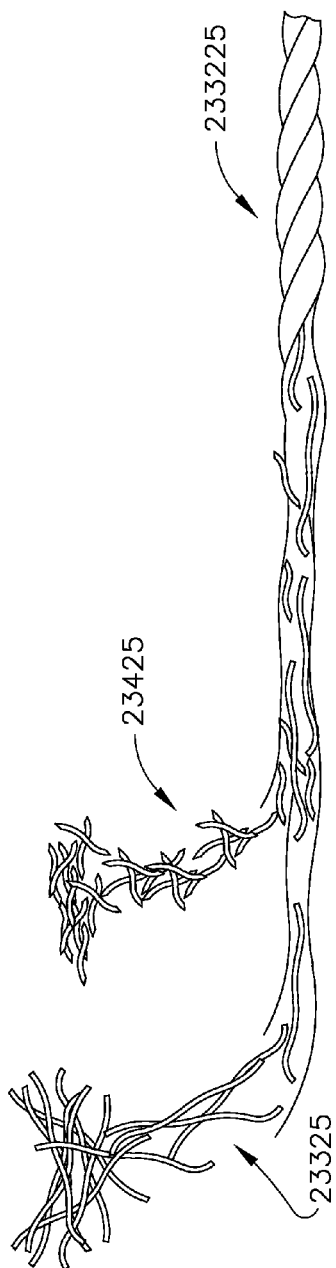


FIG. 147

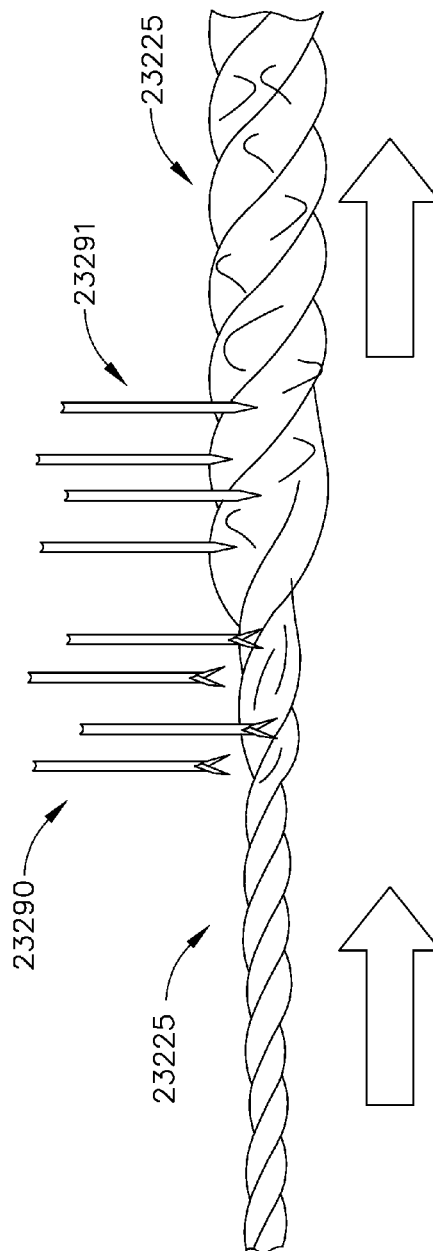


FIG. 148

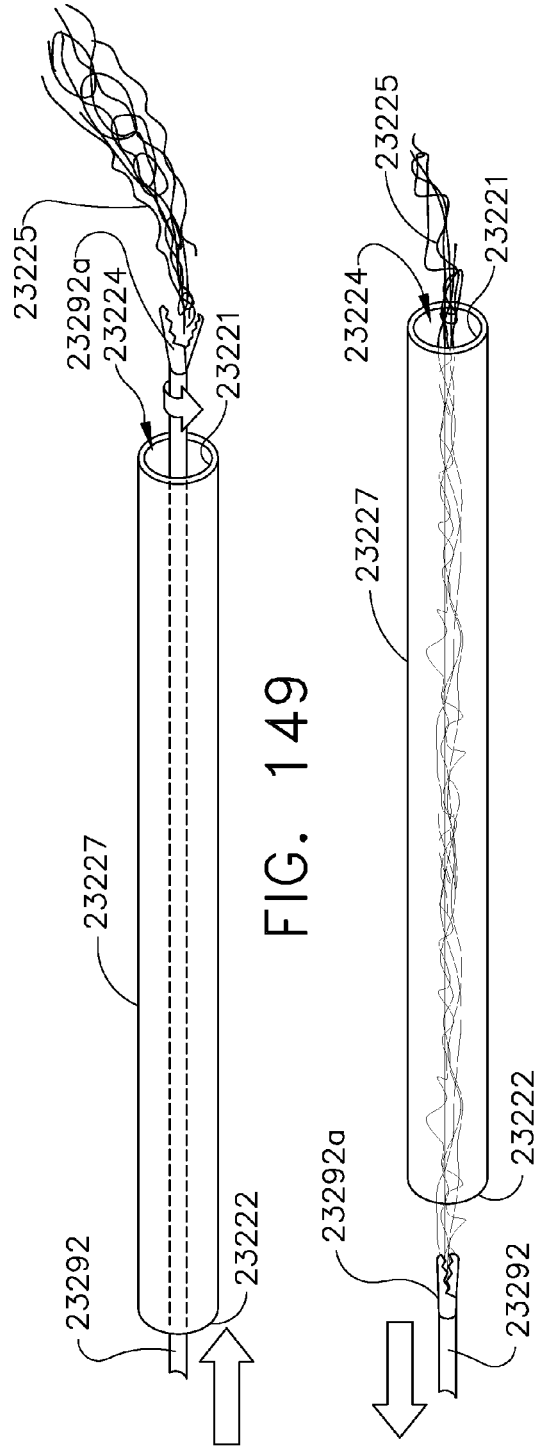


FIG. 149

FIG. 150

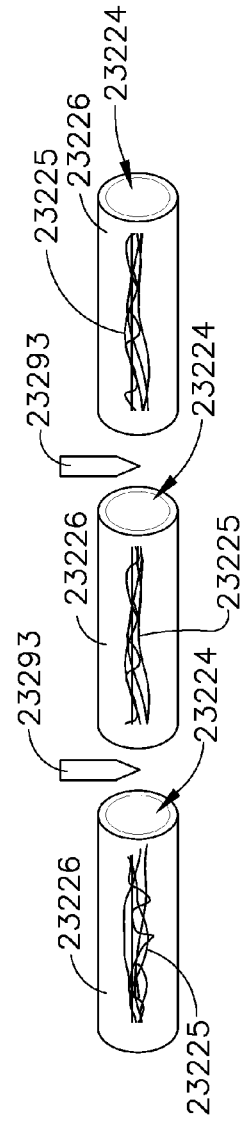


FIG. 151

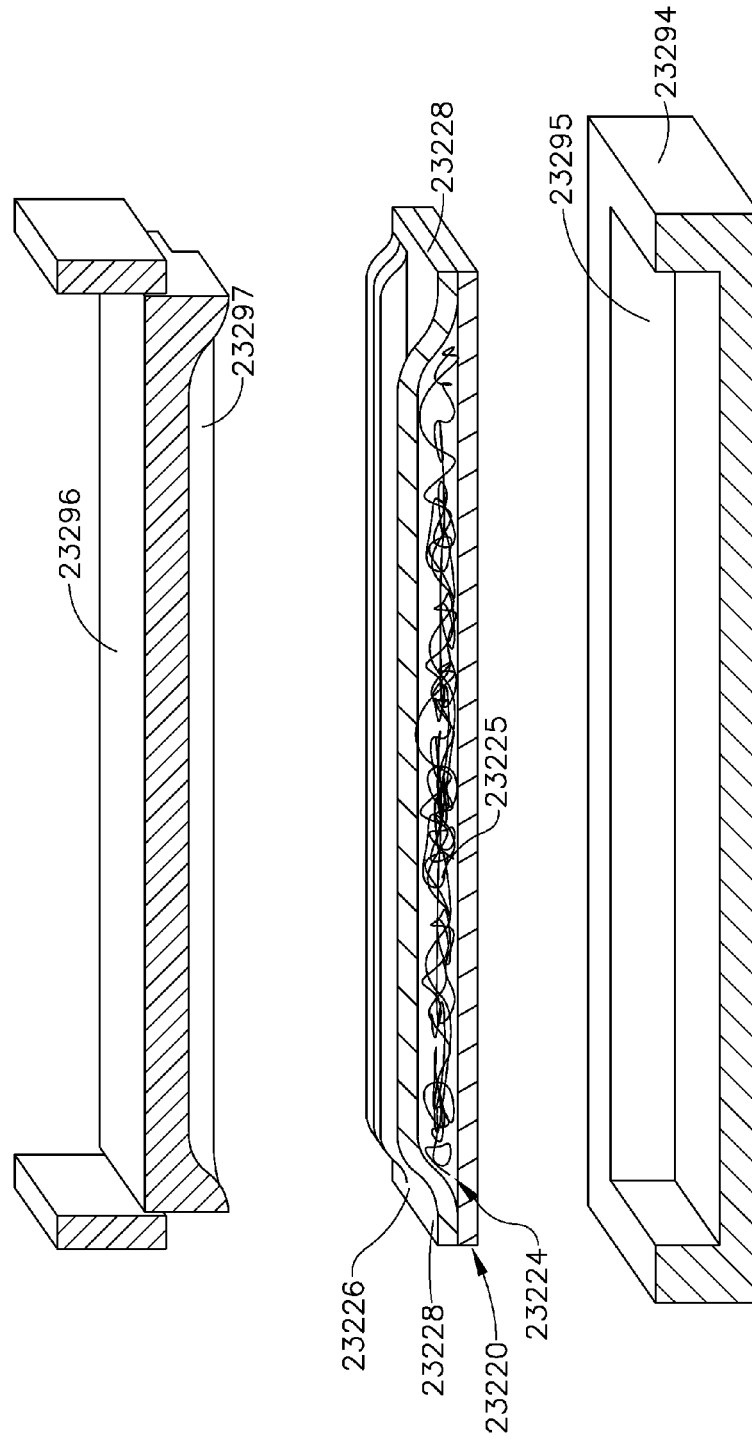


FIG. 152

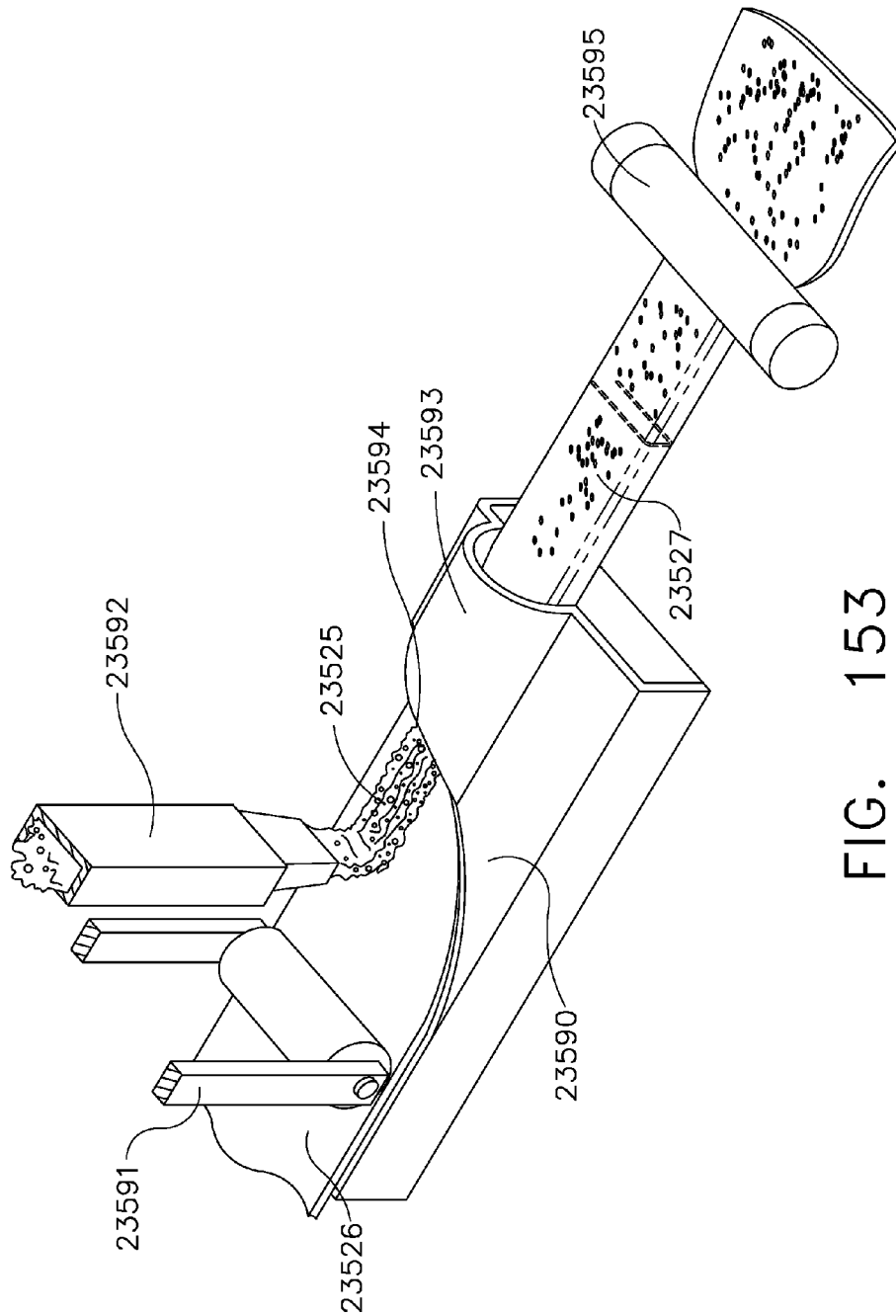


FIG. 153

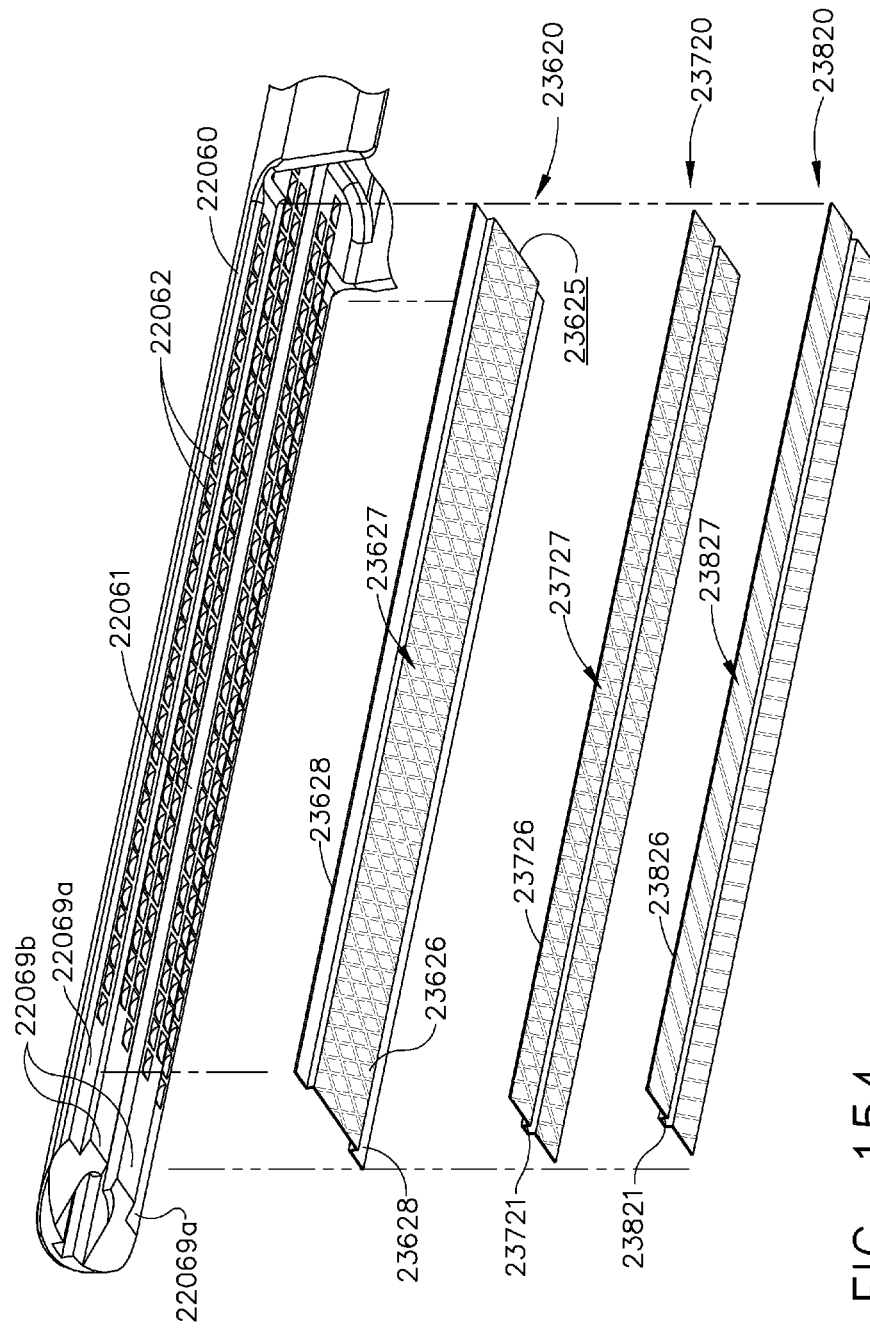


FIG. 154

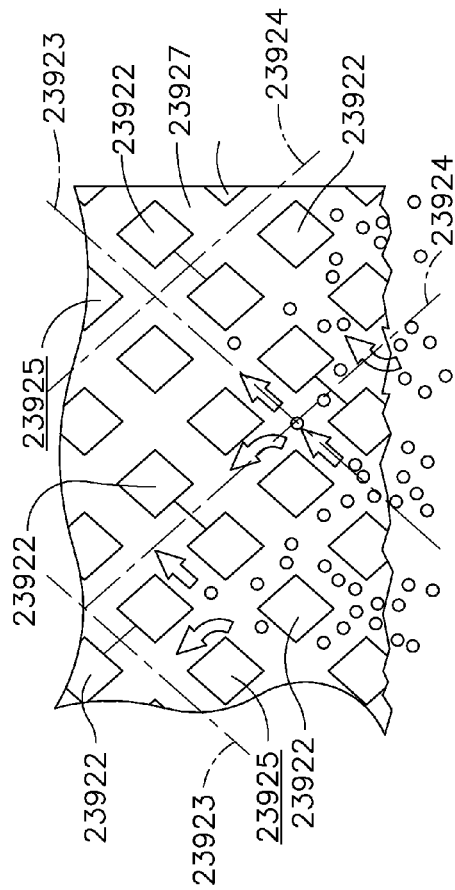


FIG. 155

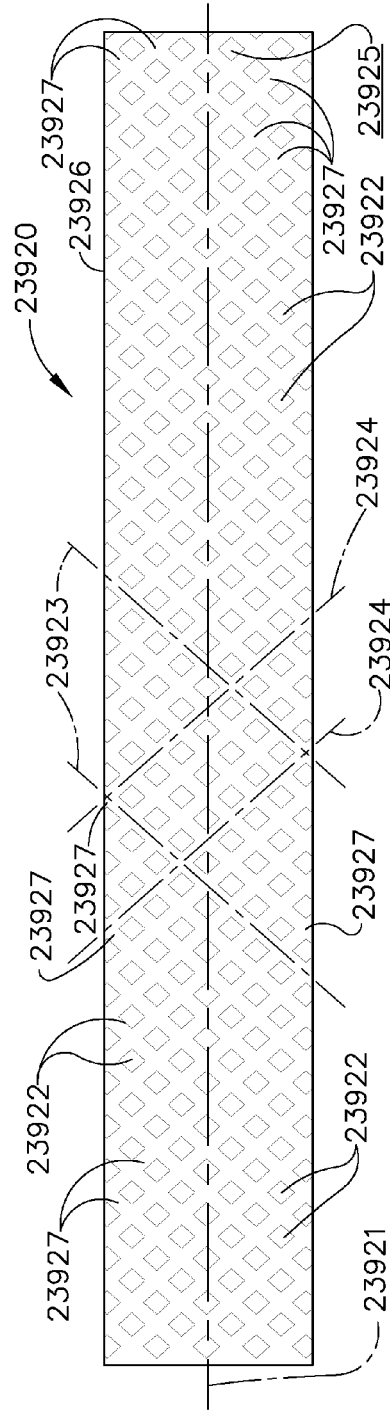


FIG. 156

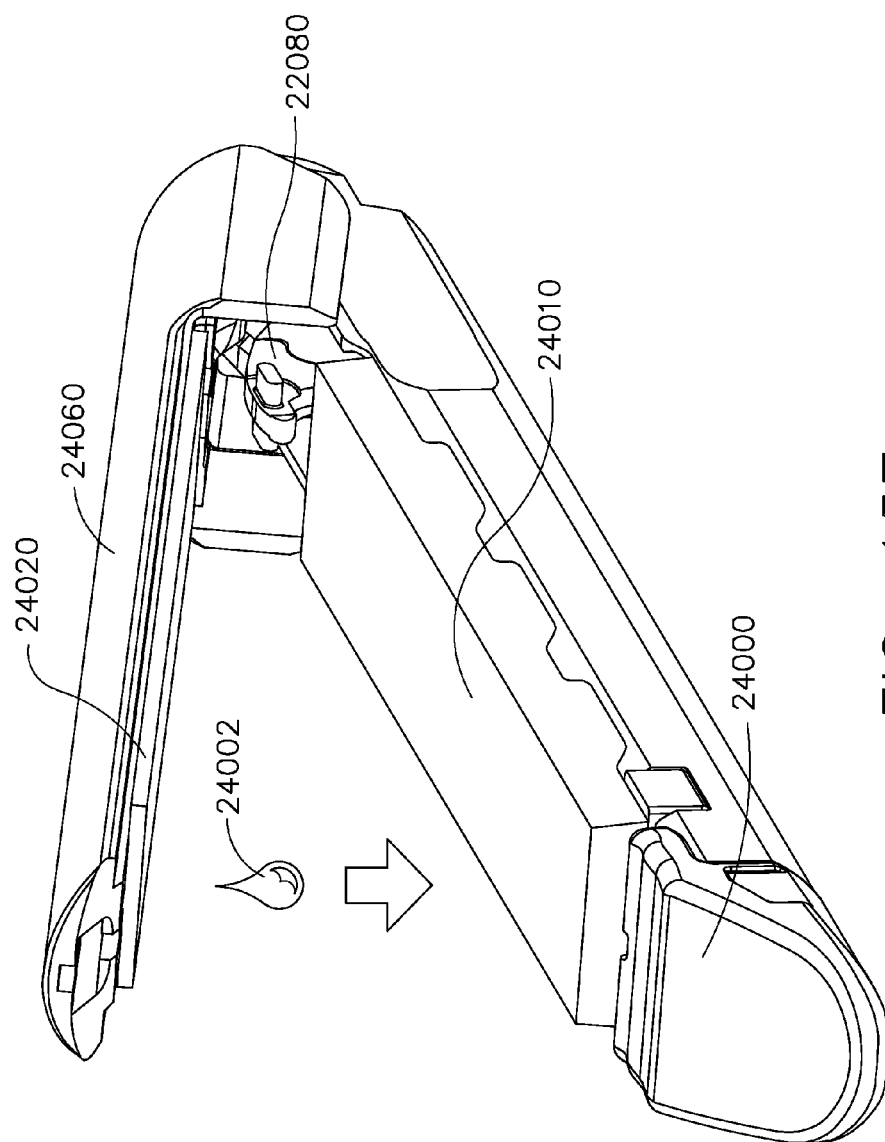


FIG. 157

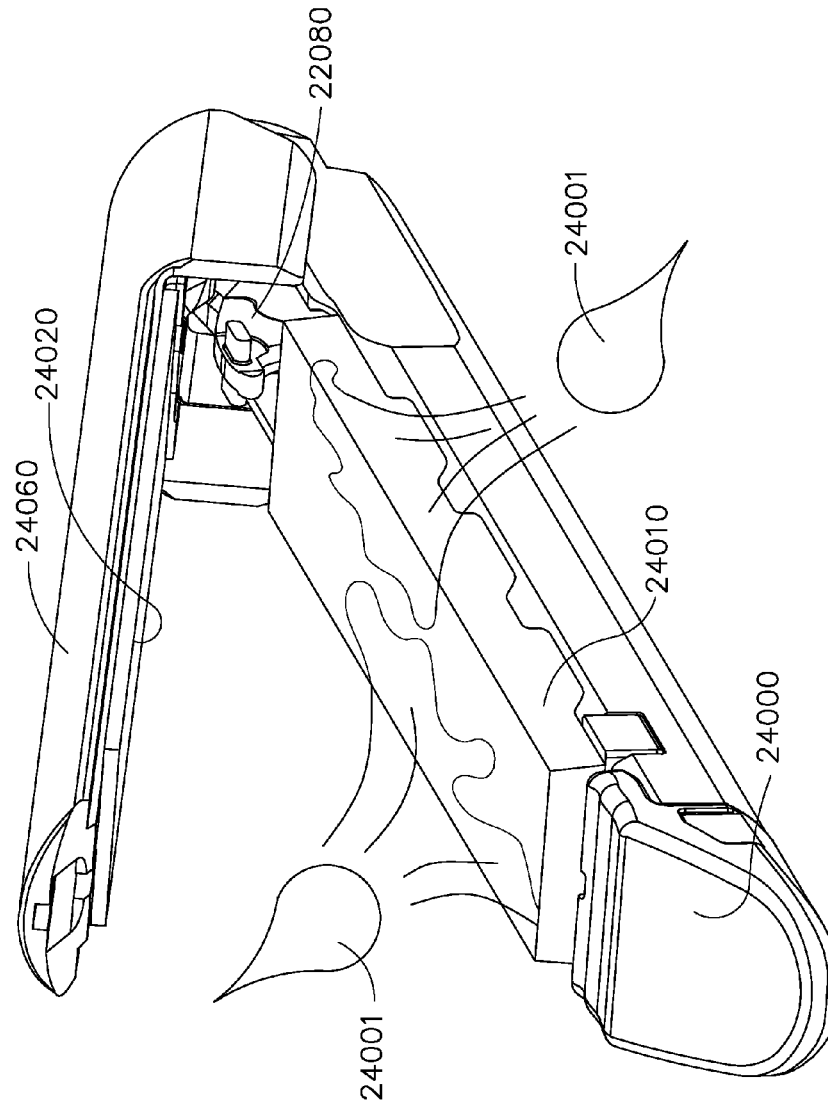


FIG. 158



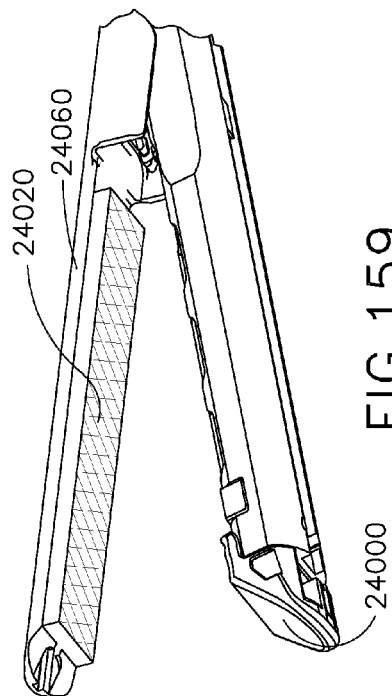


FIG. 159

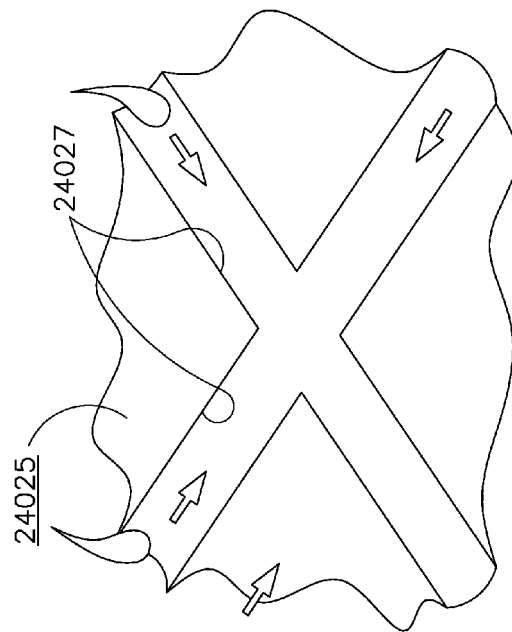
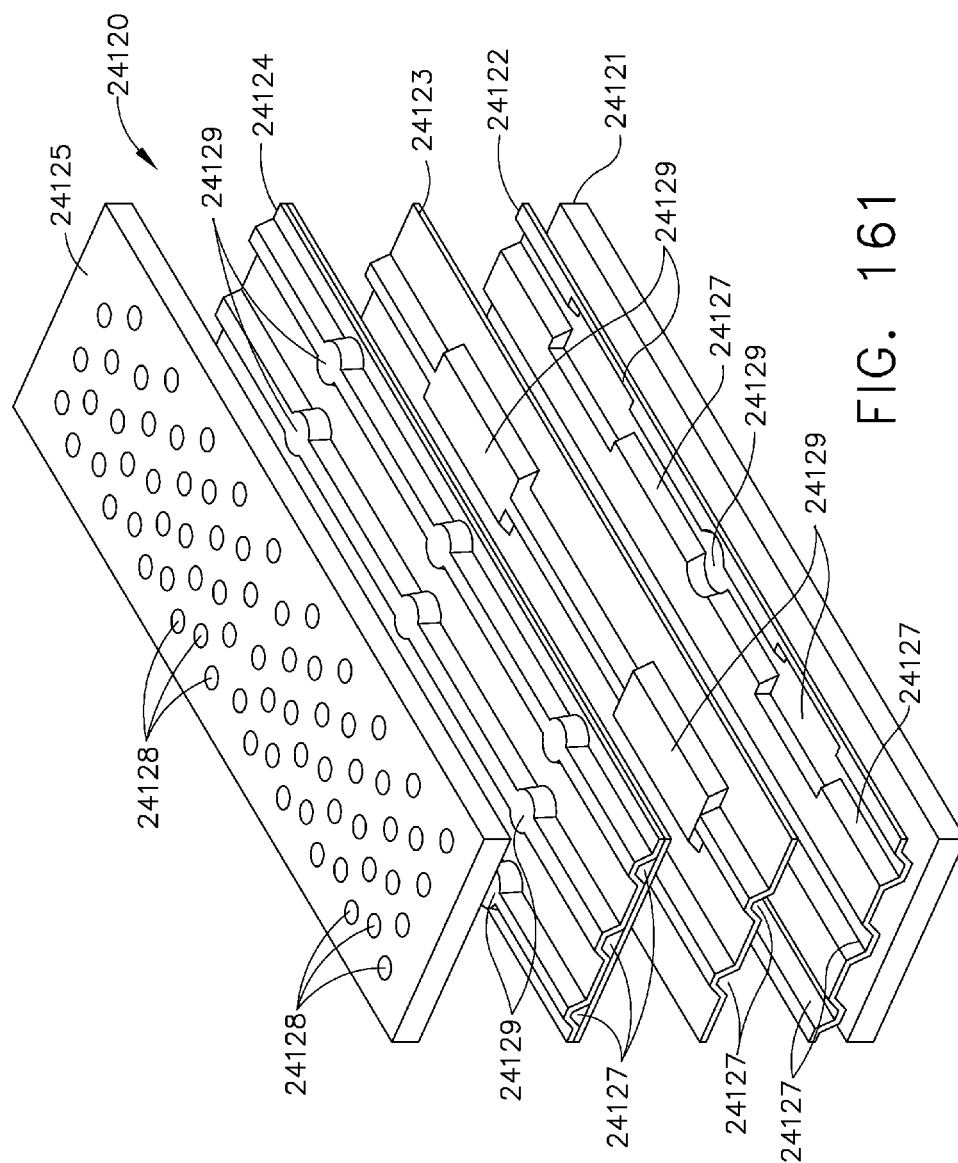


FIG. 160



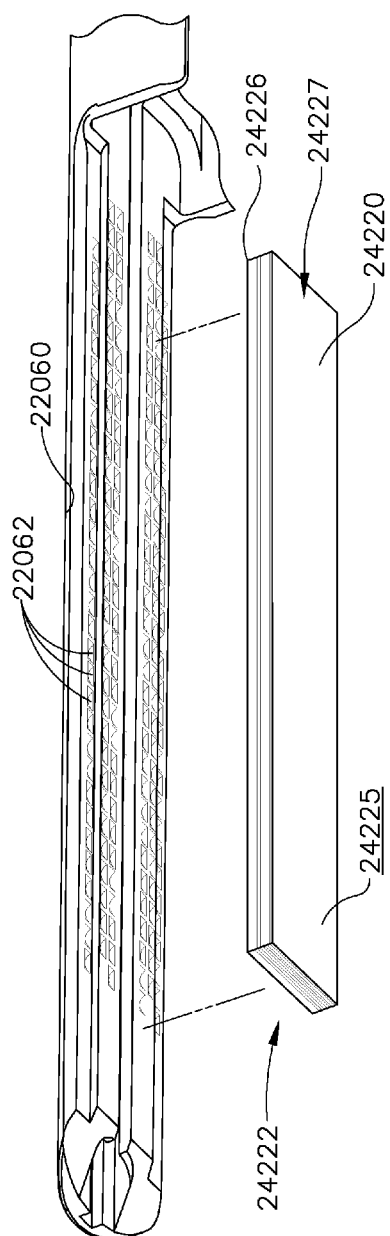


FIG. 162

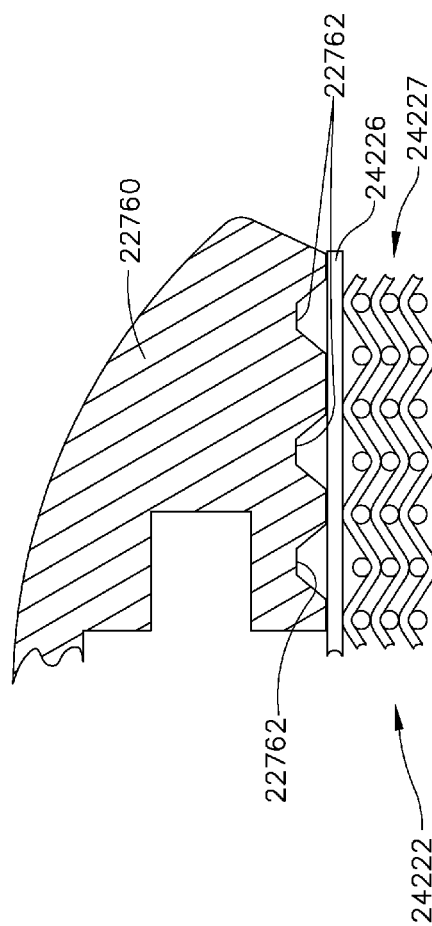


FIG. 163

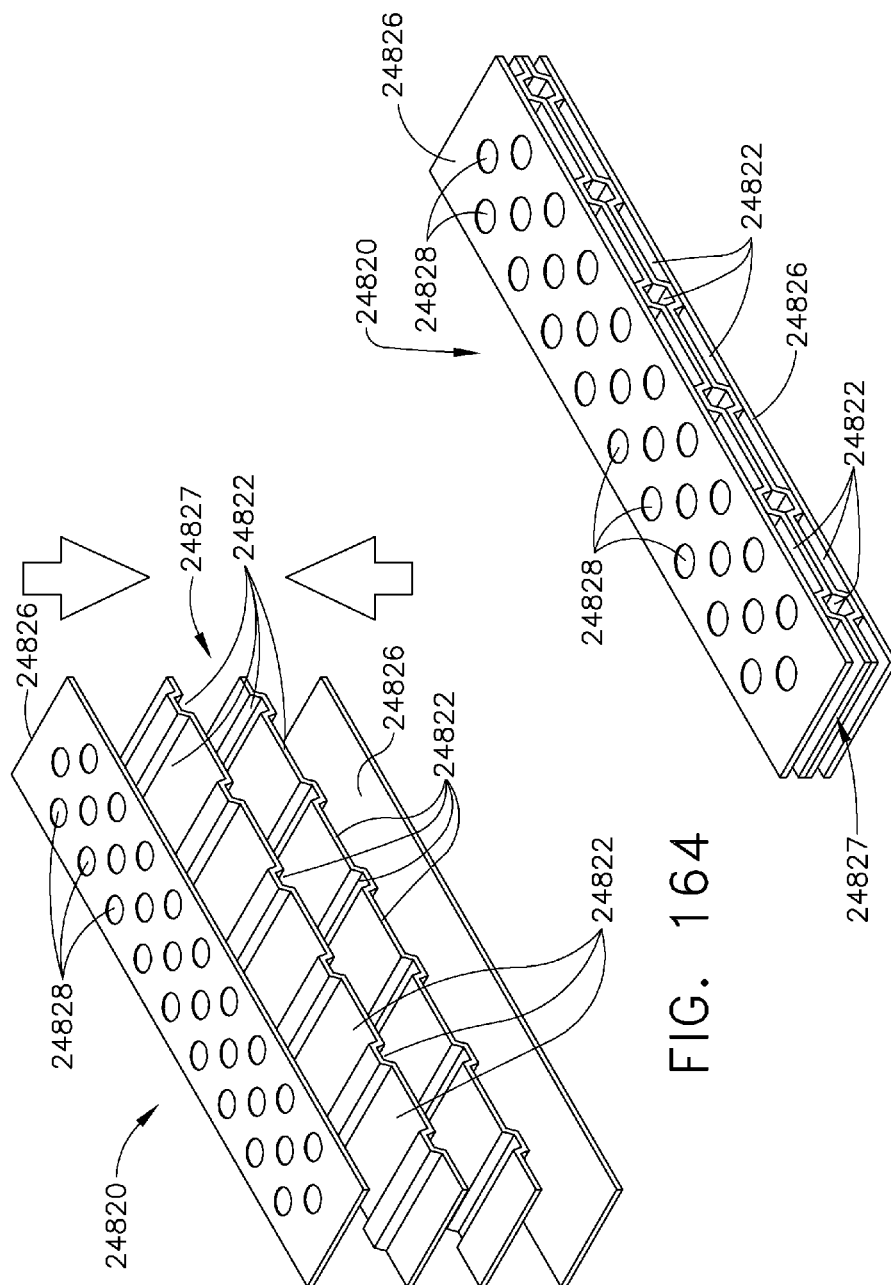


FIG. 164

FIG. 165

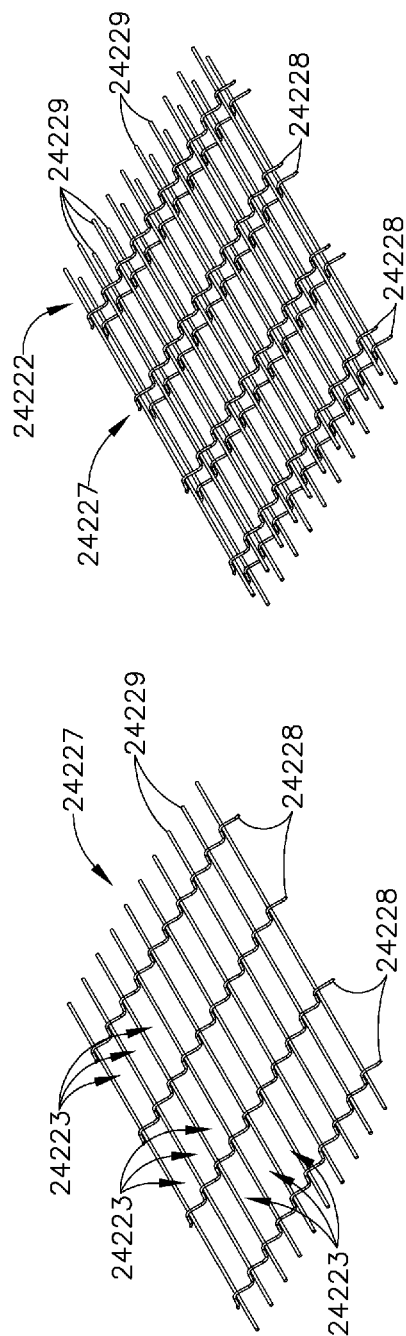


FIG. 166

FIG. 167

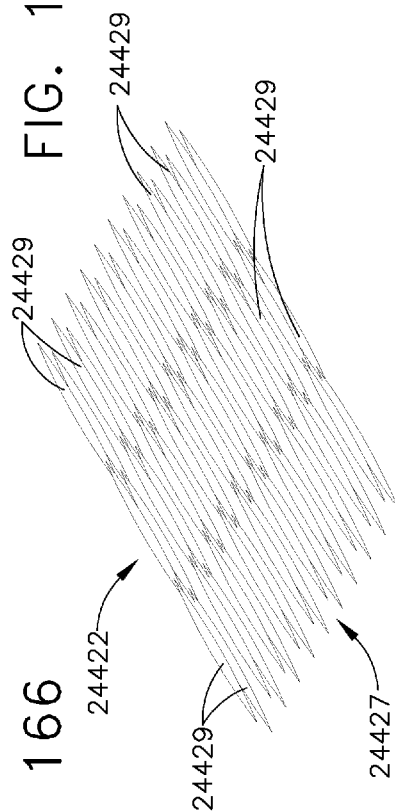


FIG. 168

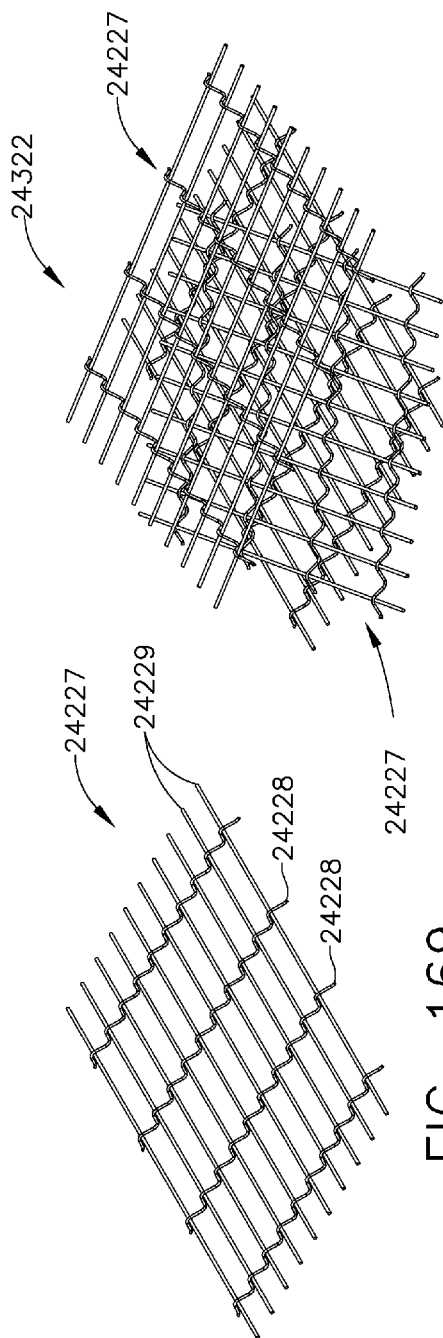
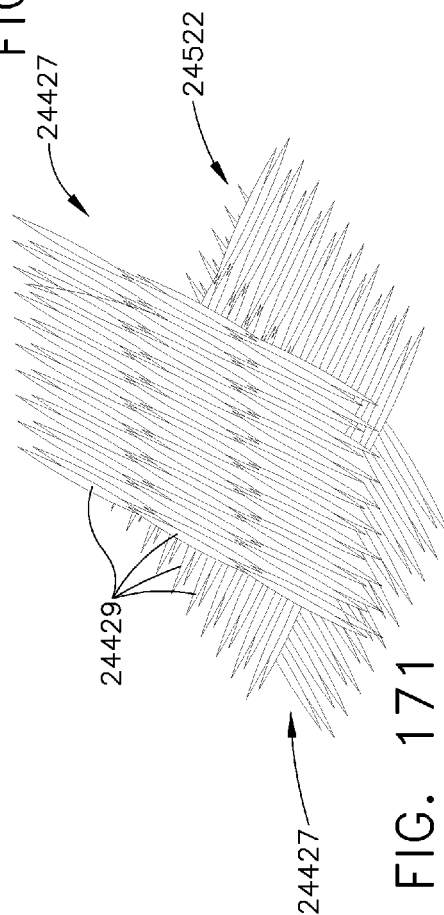


FIG. 170



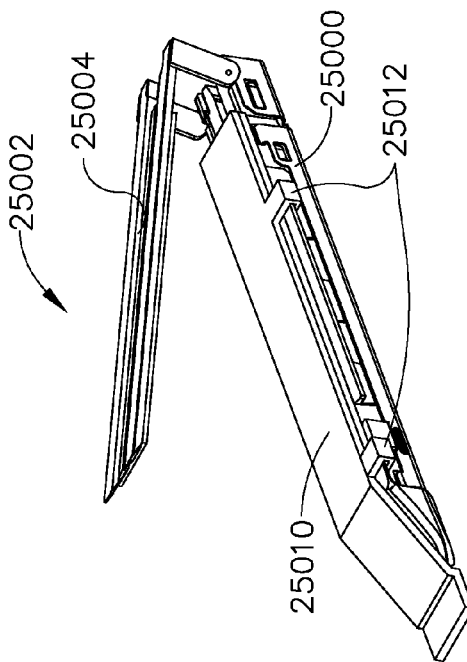
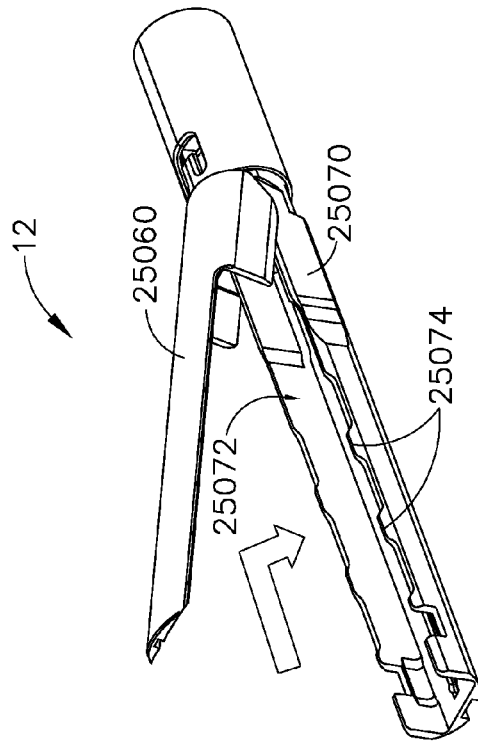
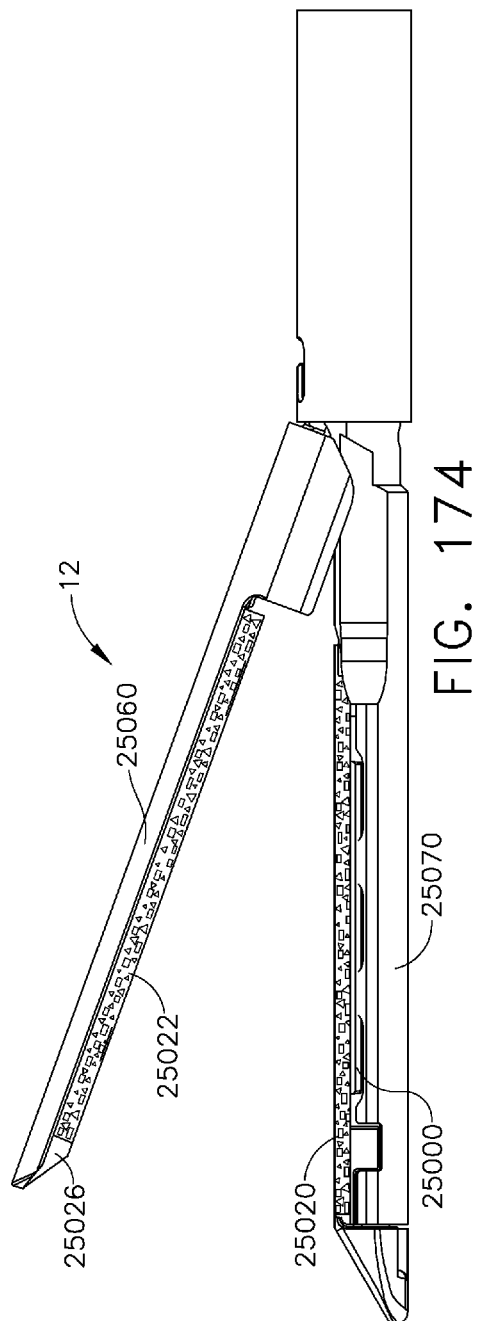
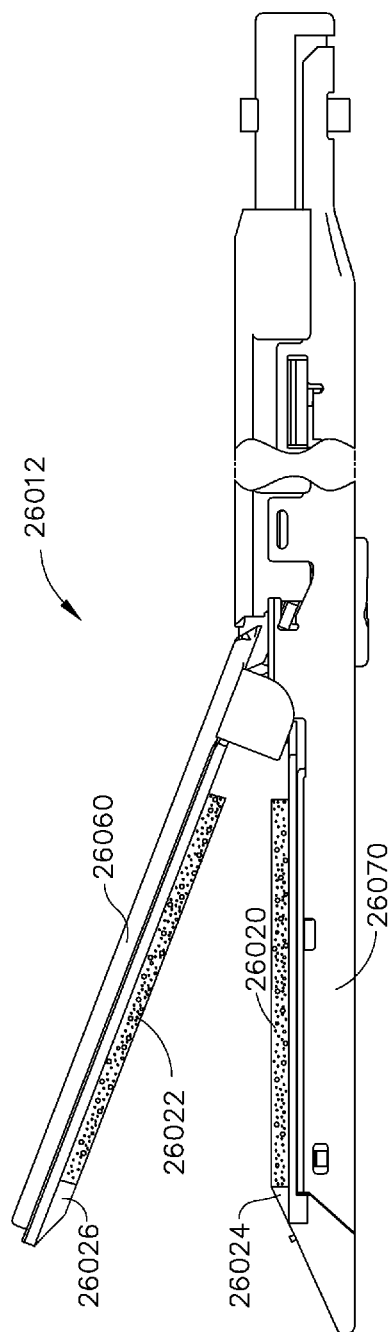


FIG. 172





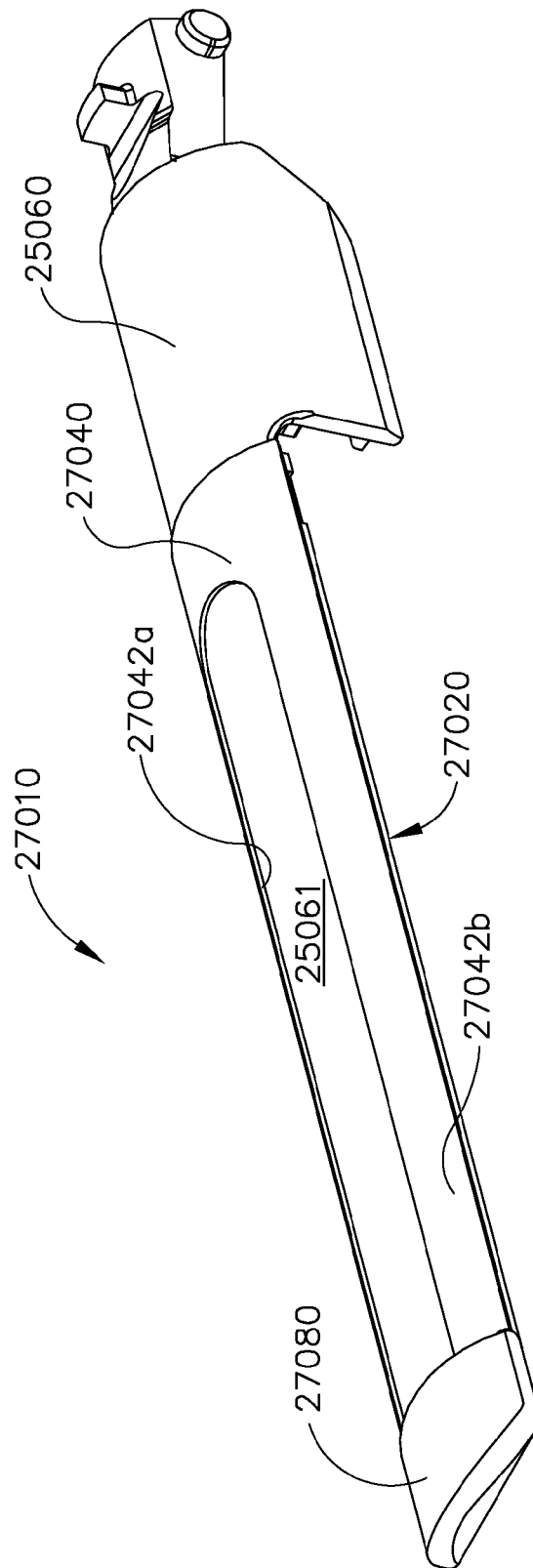


FIG. 175

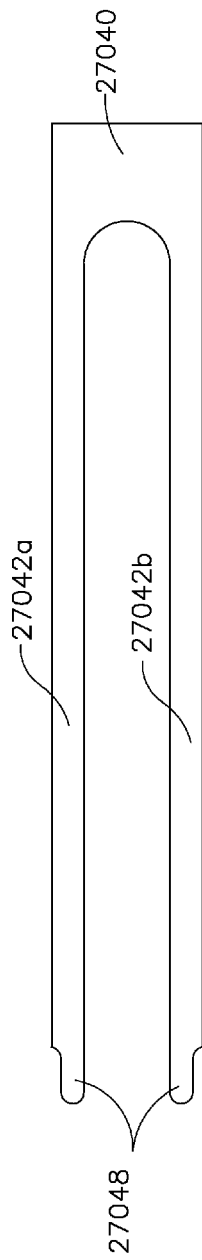


FIG. 176

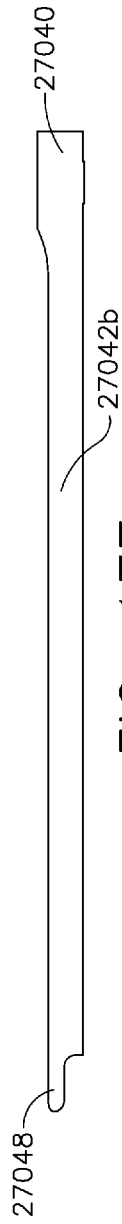


FIG. 177

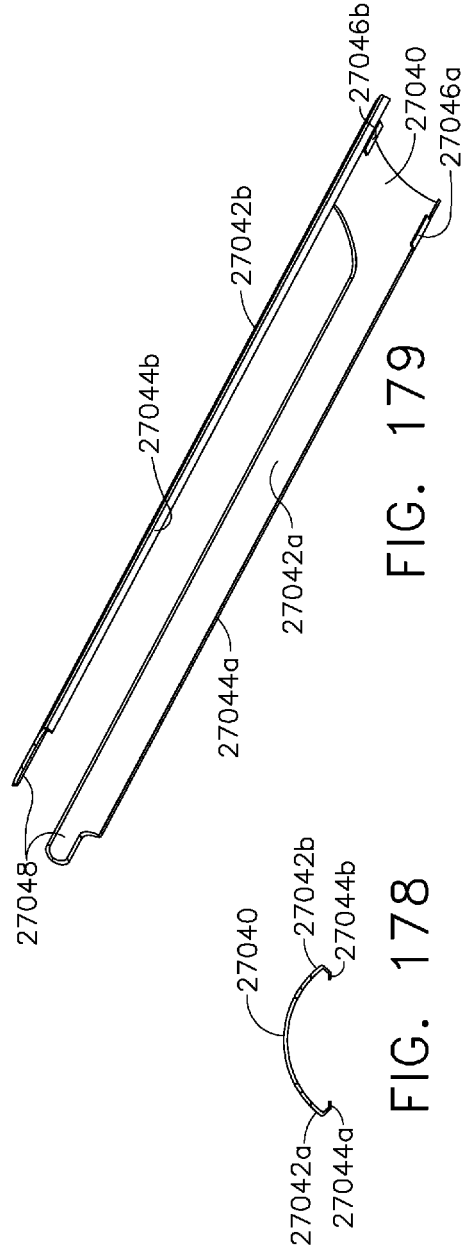


FIG. 178

FIG. 179

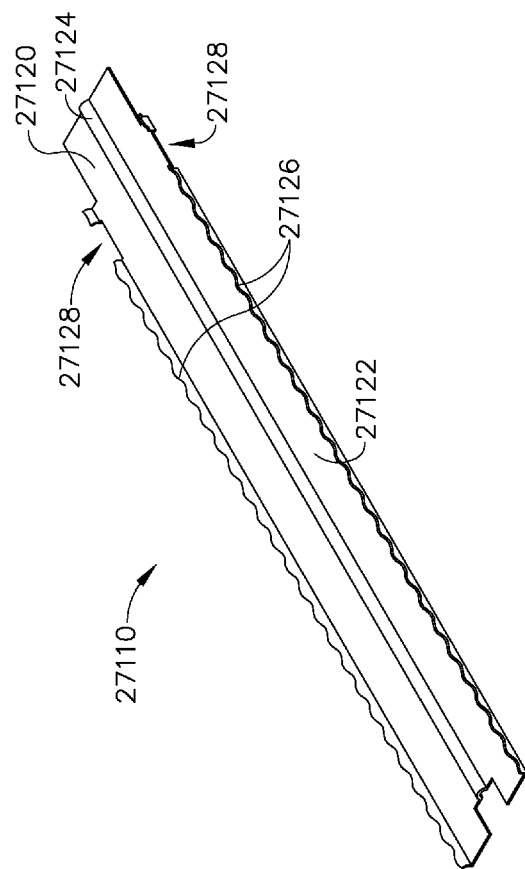


FIG. 181

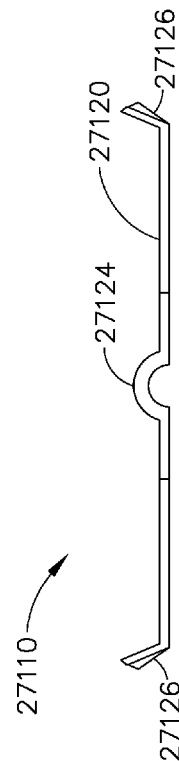


FIG. 182

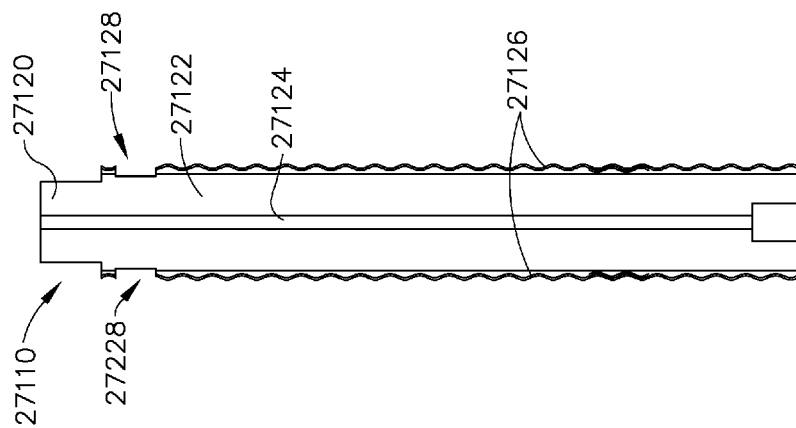


FIG. 180

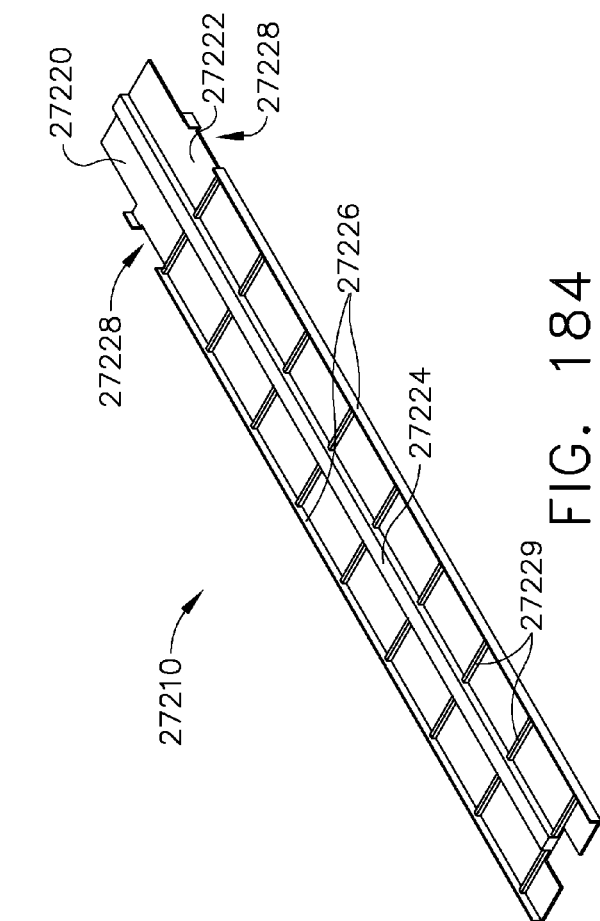


FIG. 183

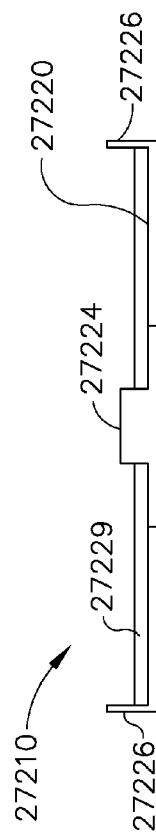


FIG. 184

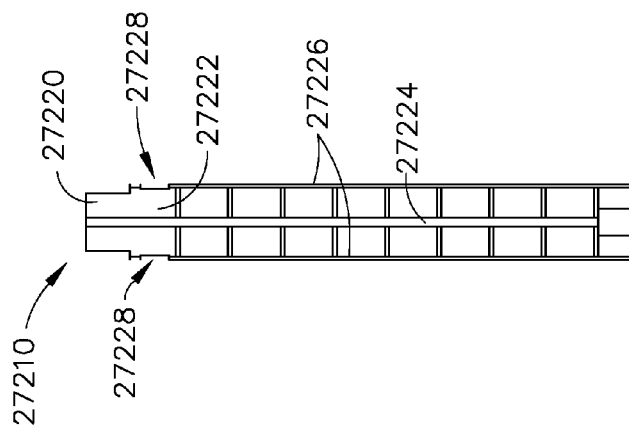


FIG. 185

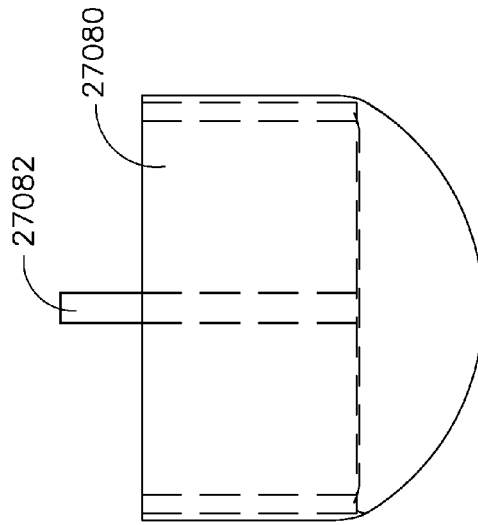


FIG. 188

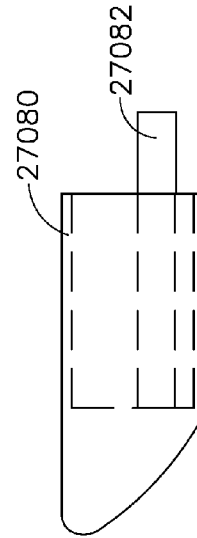


FIG. 189

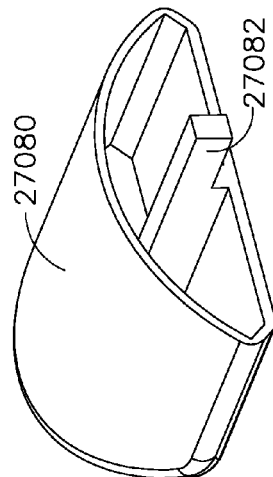


FIG. 186

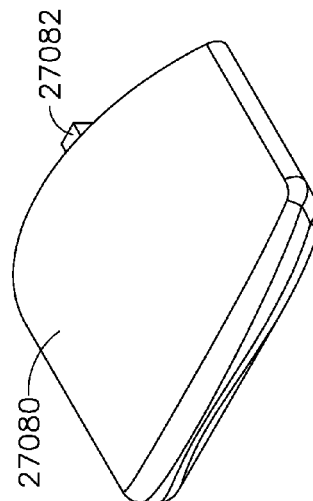


FIG. 187

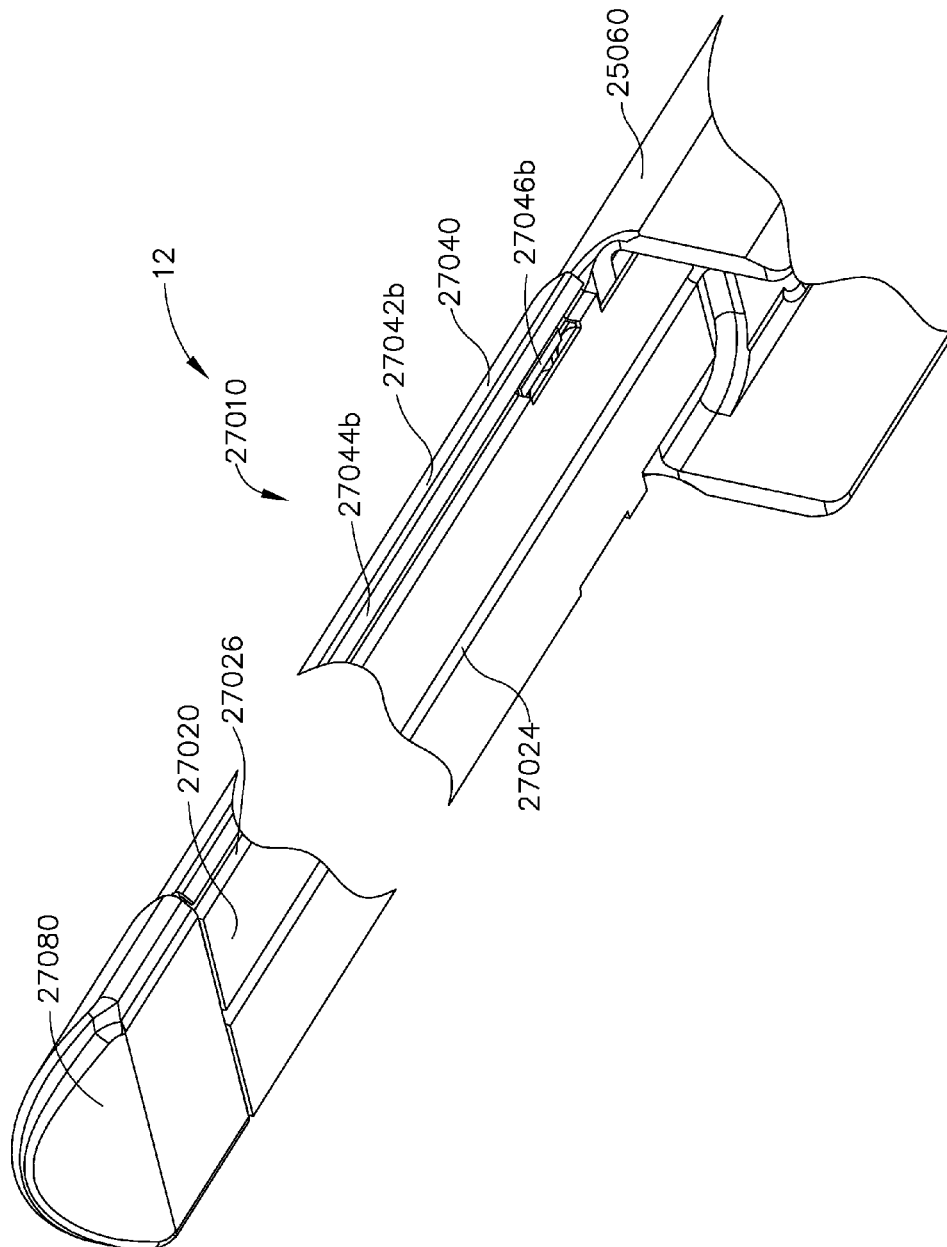
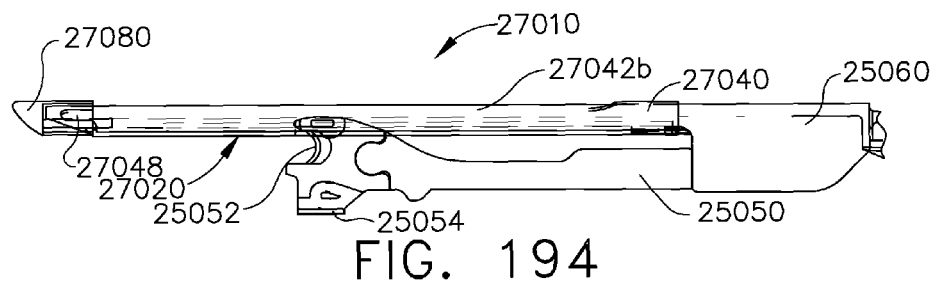
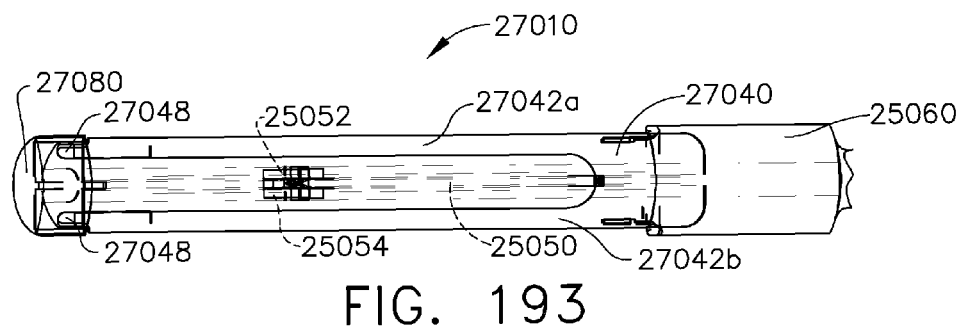
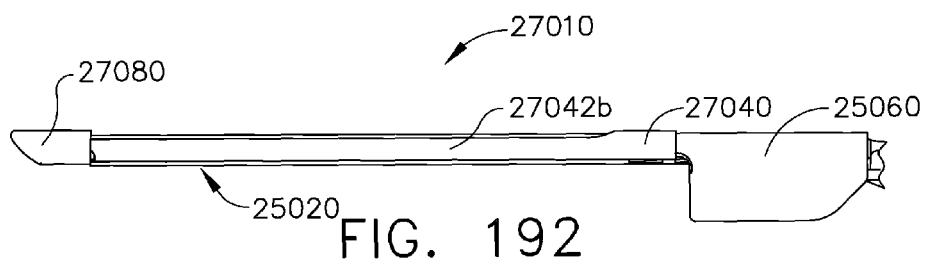
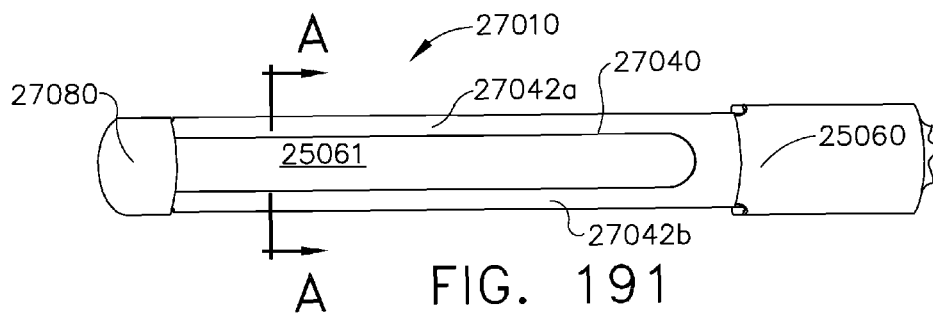
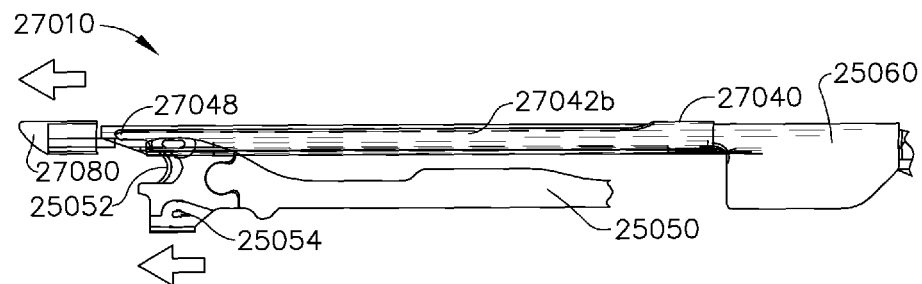
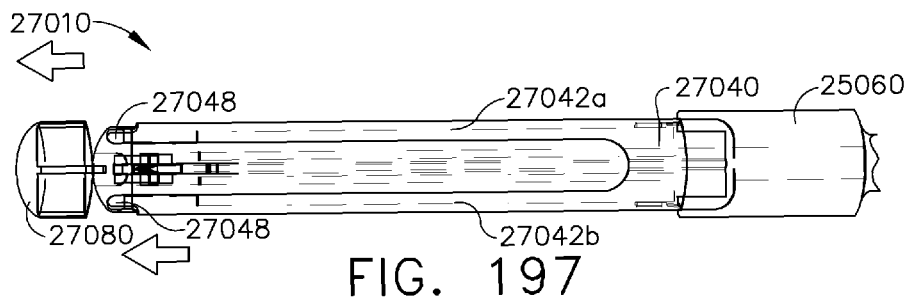
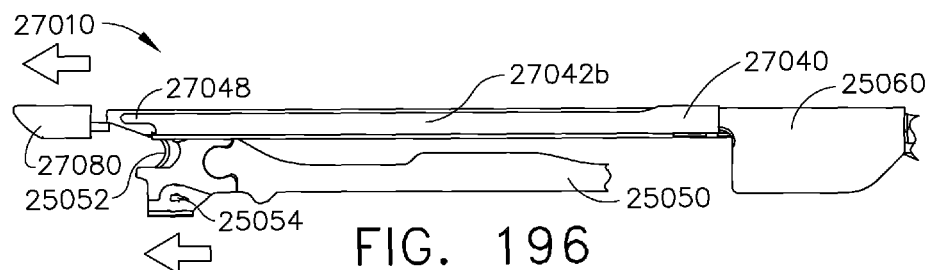
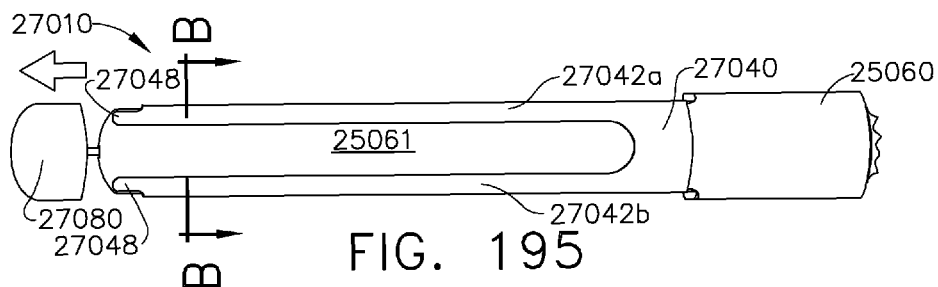
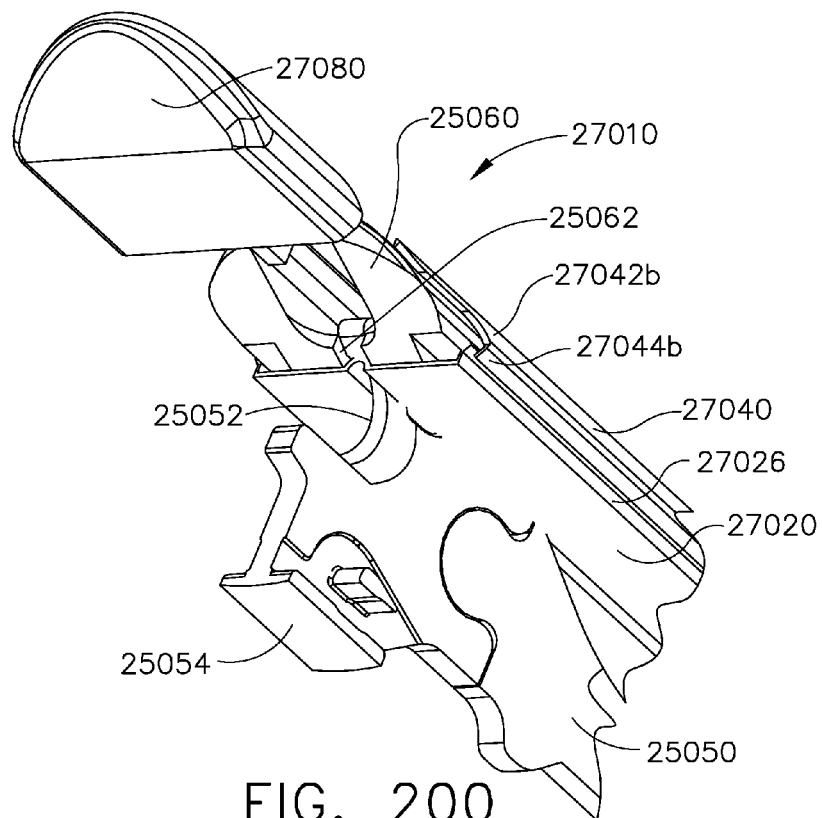
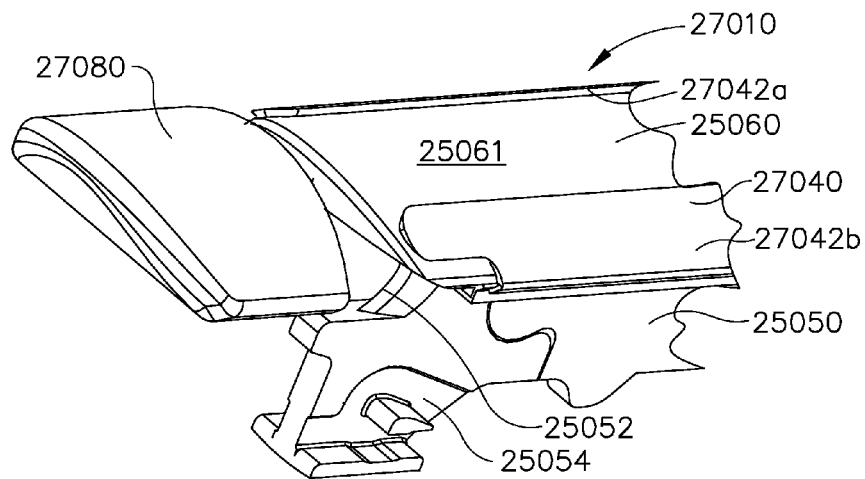


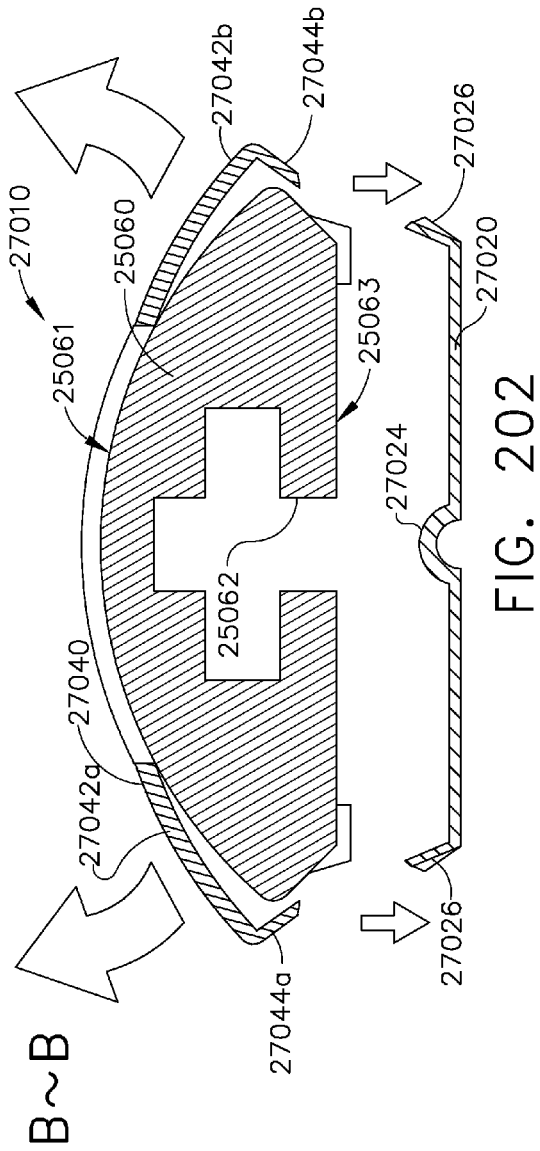
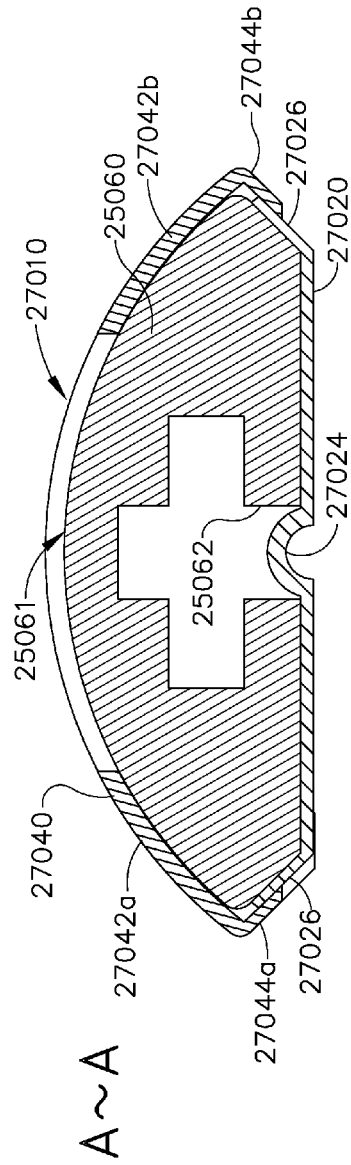
FIG. 190











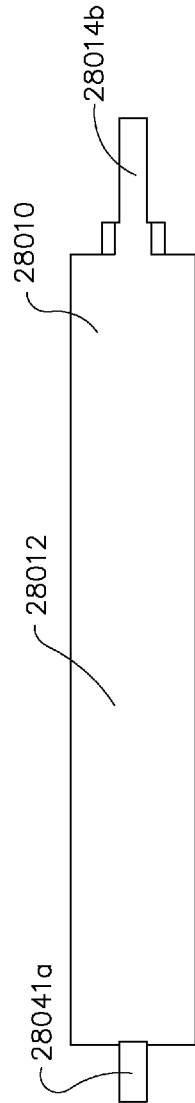


FIG. 203

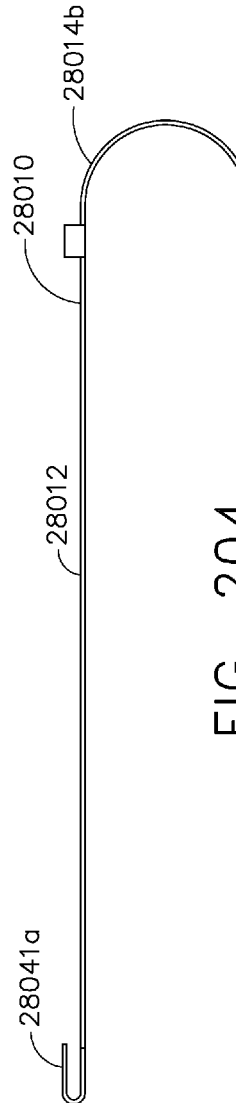


FIG. 204

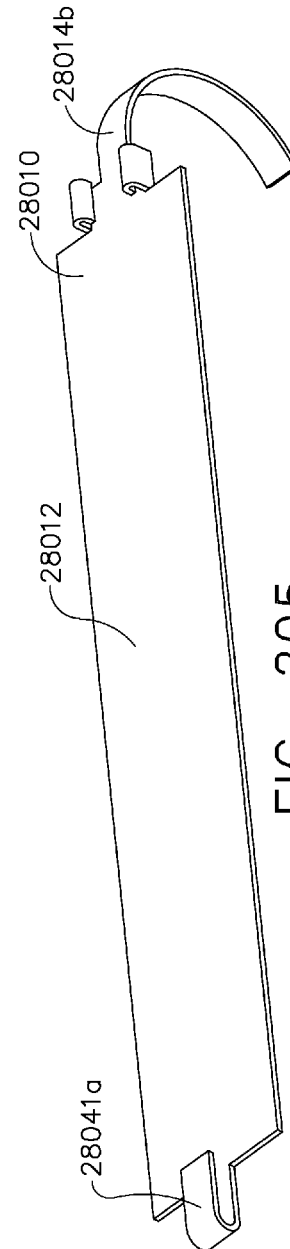
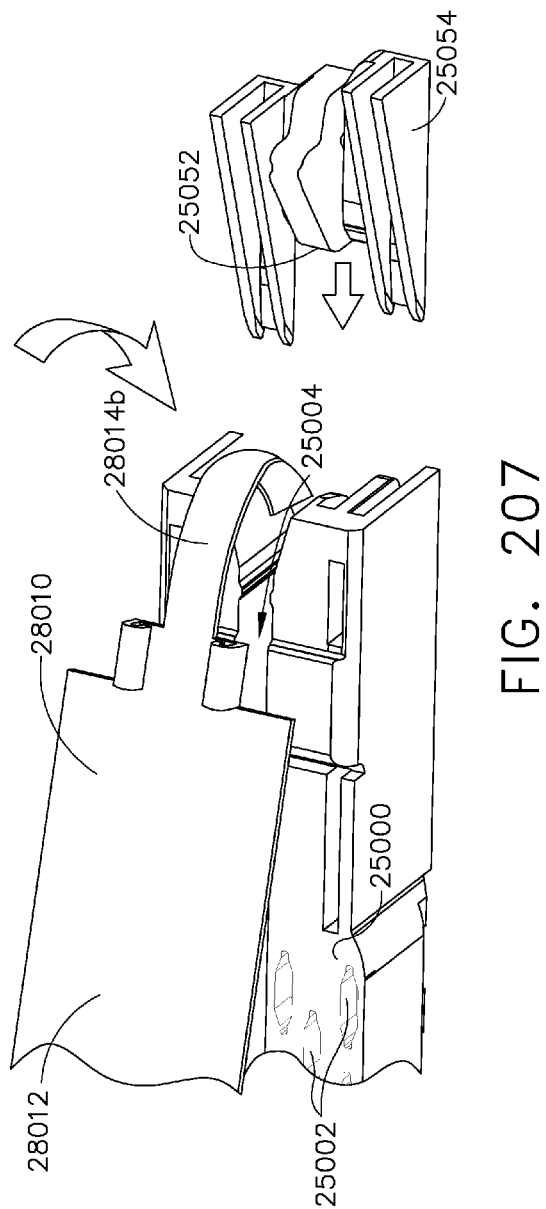
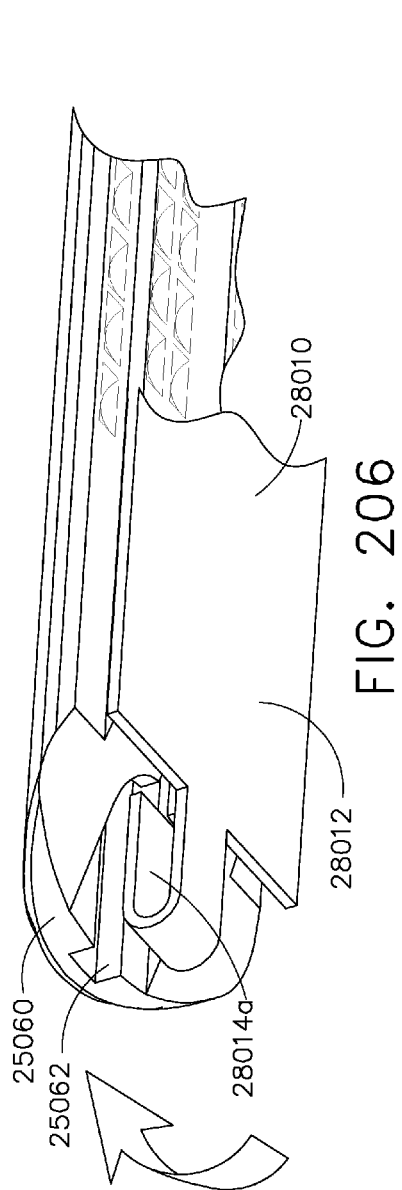


FIG. 205



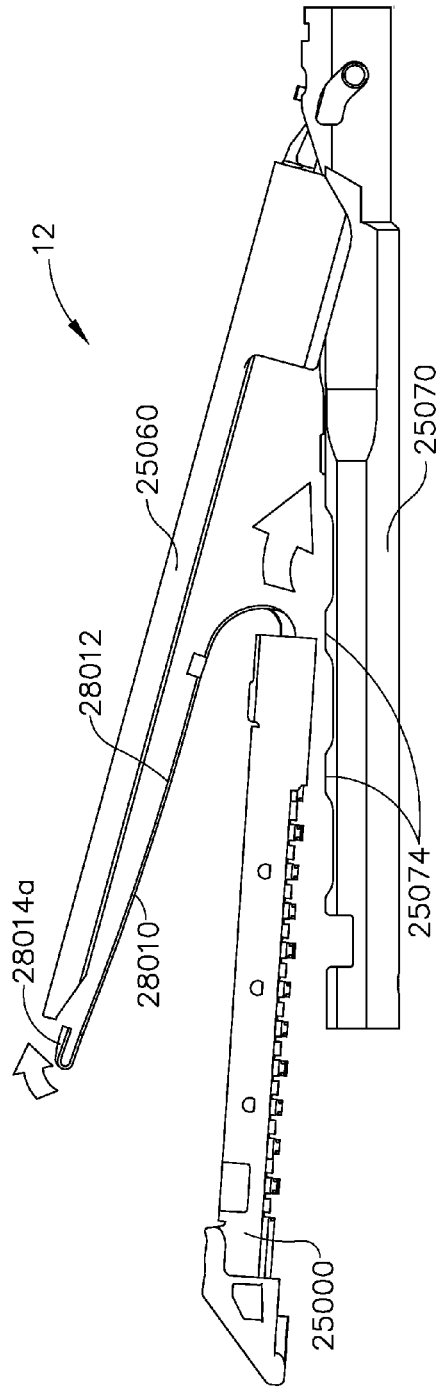


FIG. 208

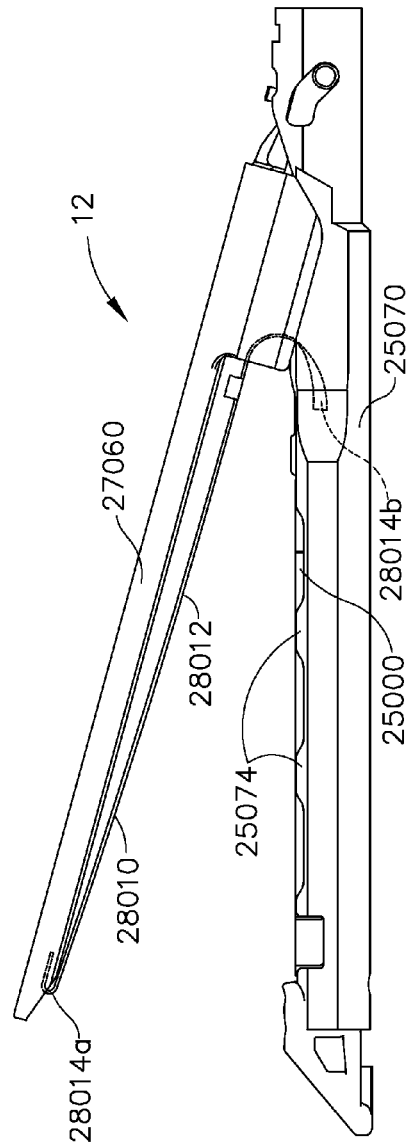
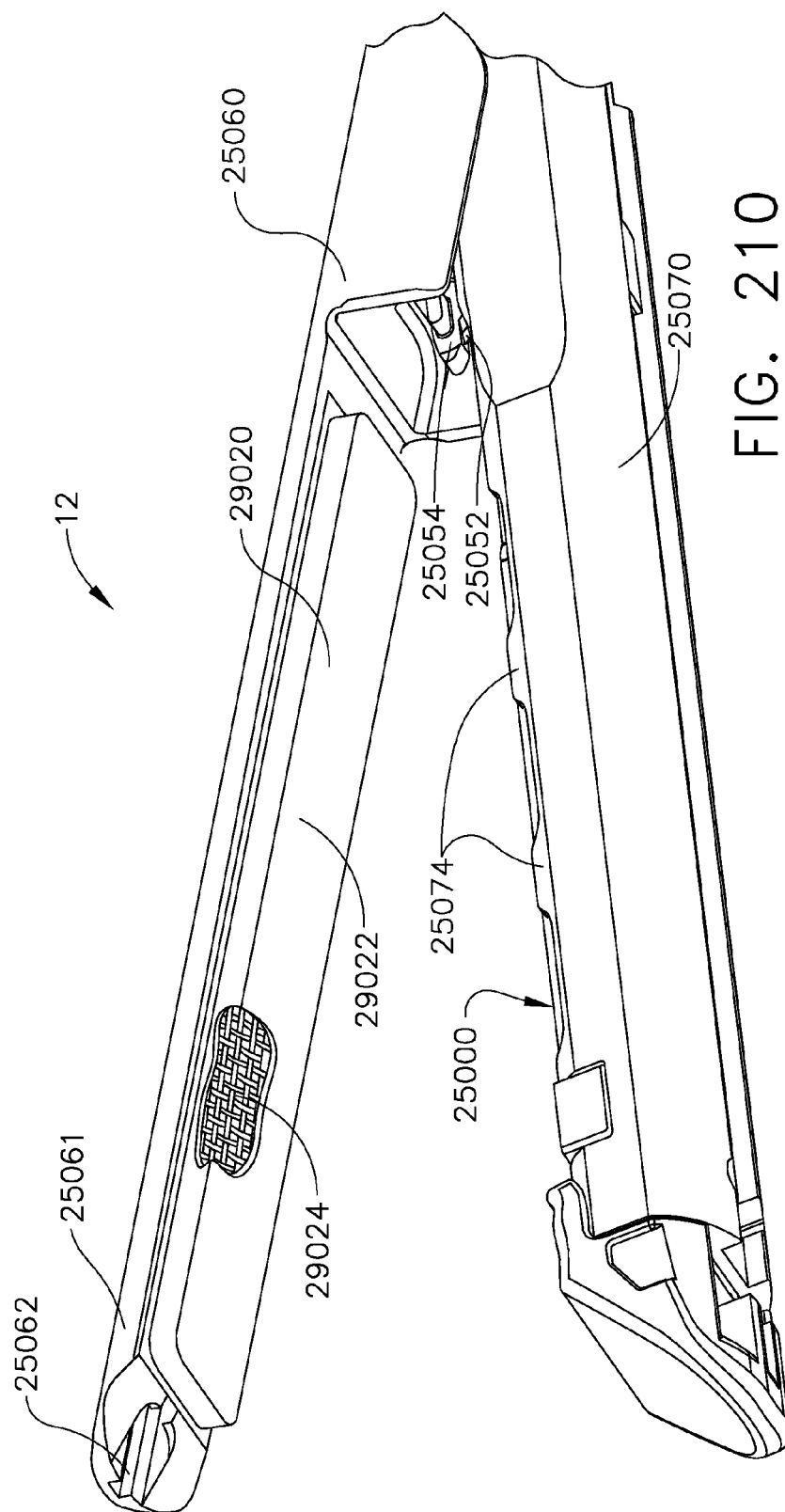


FIG. 209



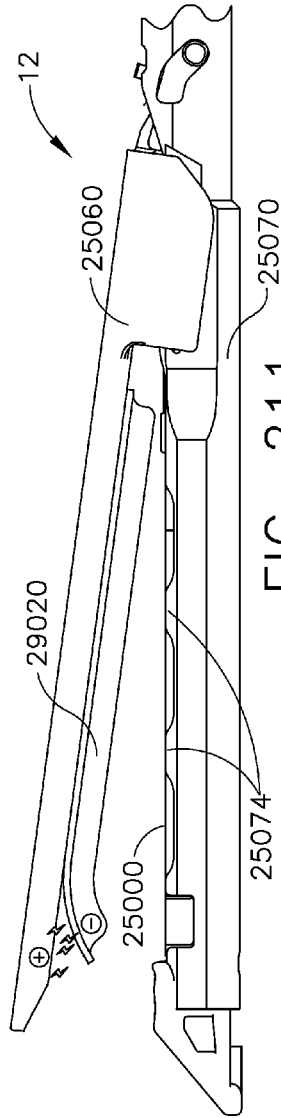


FIG. 211

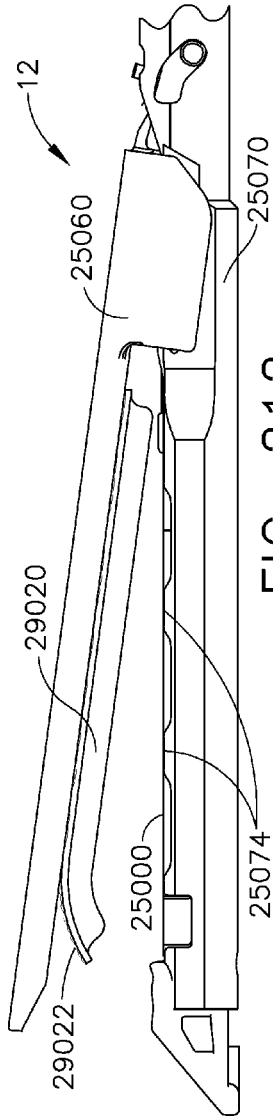


FIG. 212

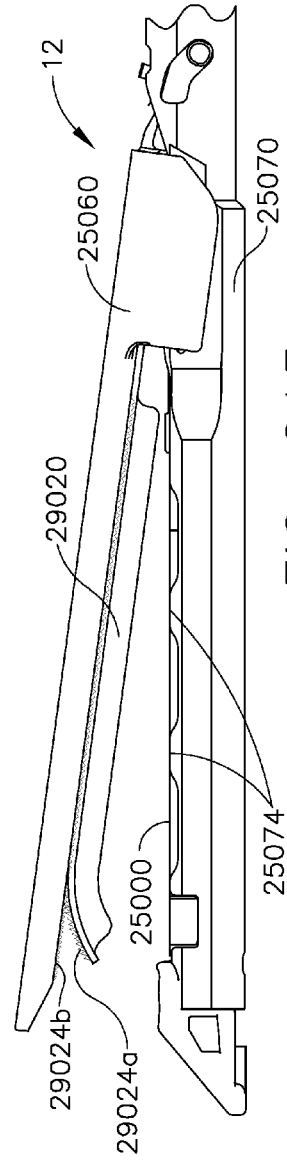


FIG. 213

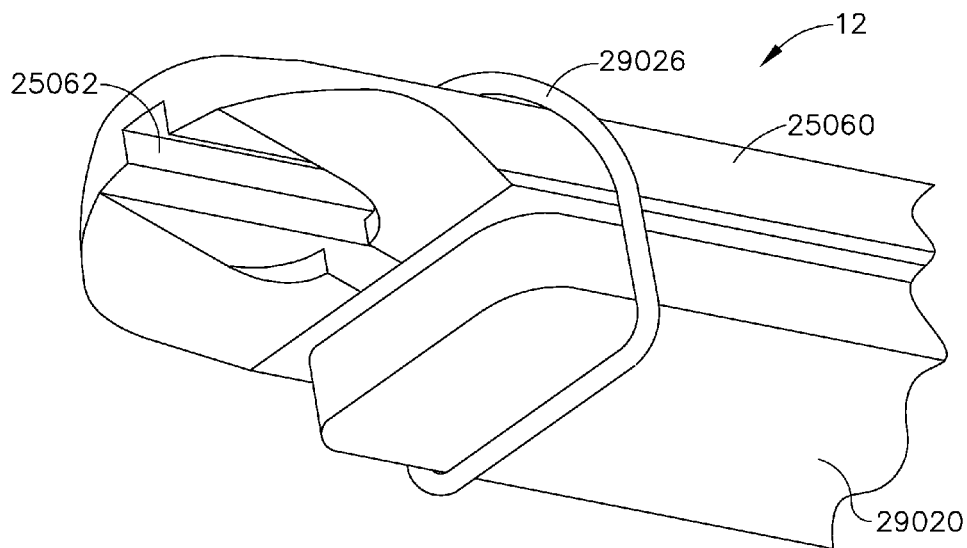


FIG. 214

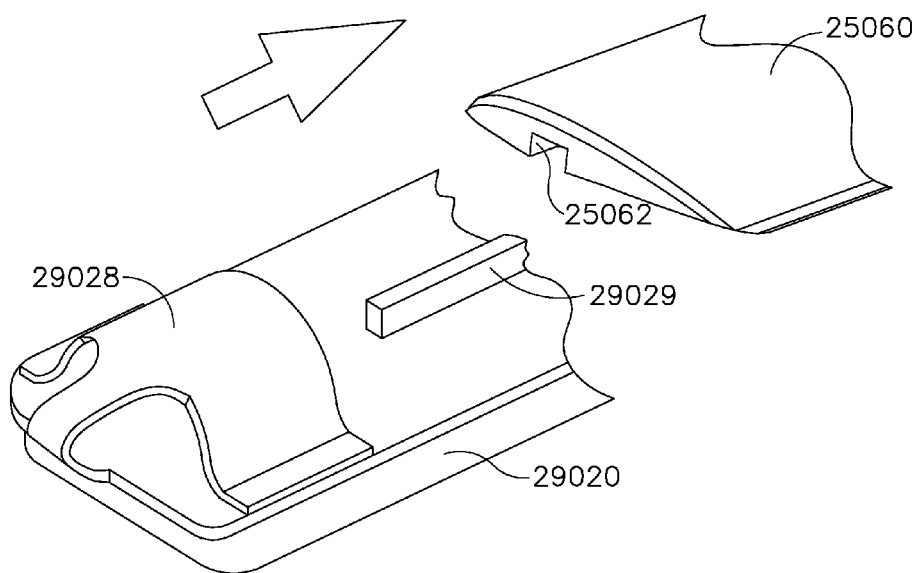


FIG. 215



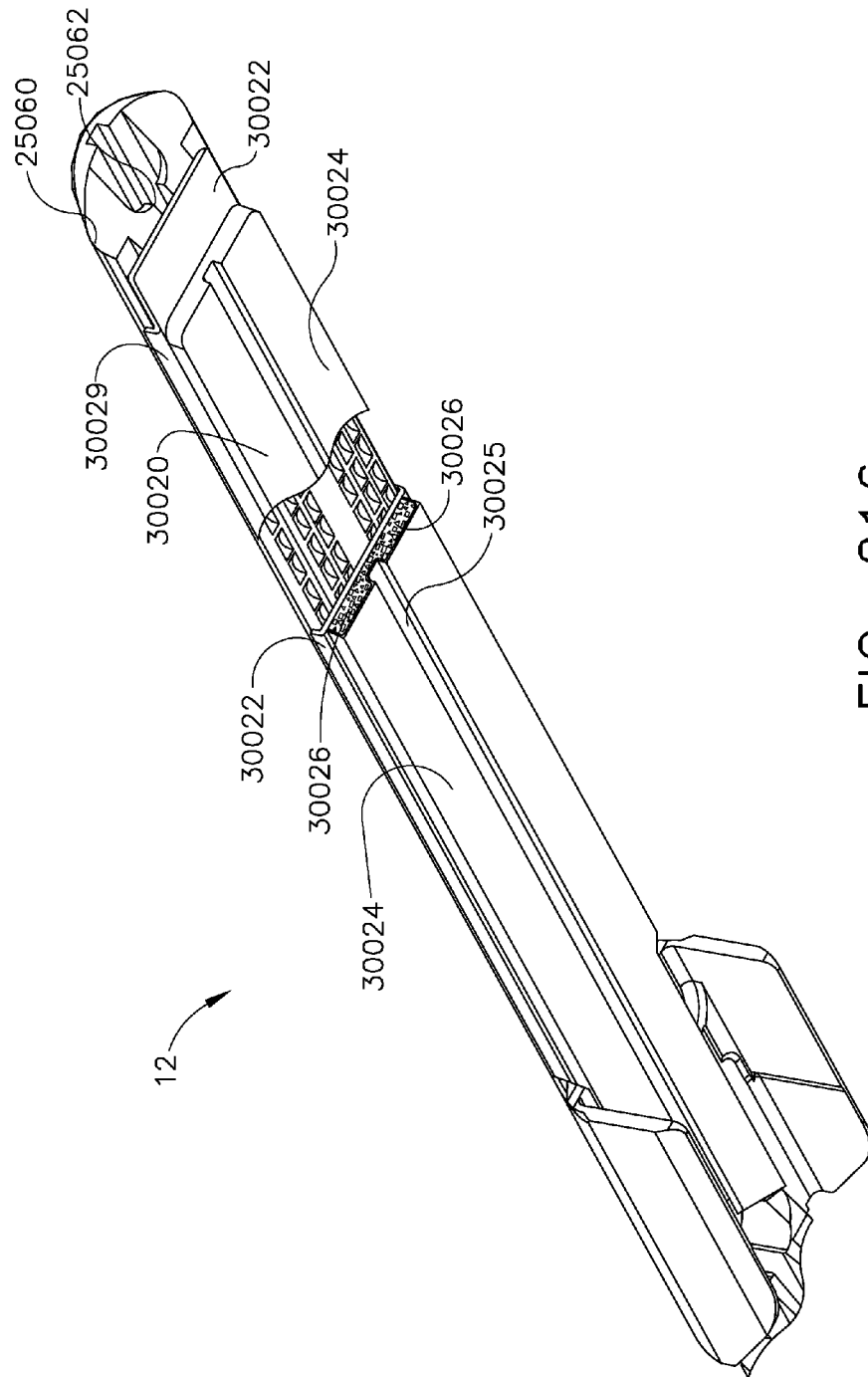


FIG. 216

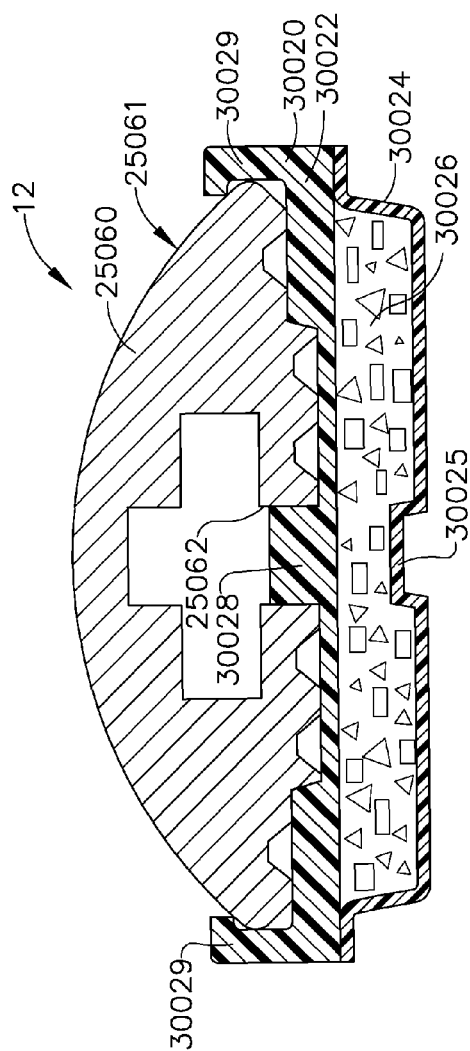


FIG. 217

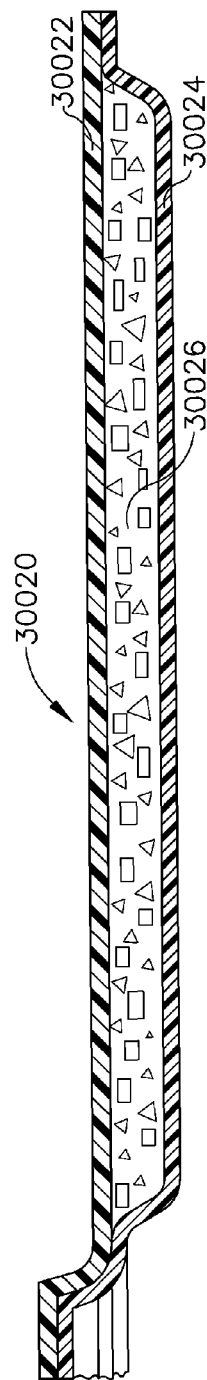


FIG. 218

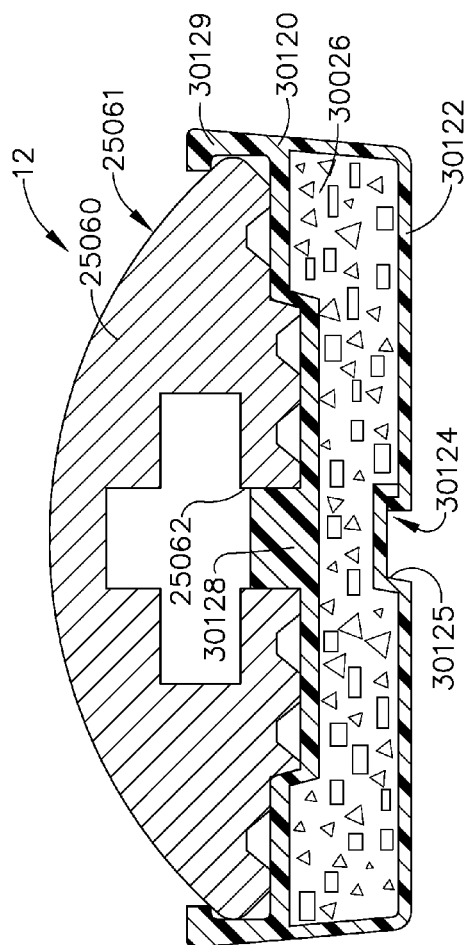


FIG. 219

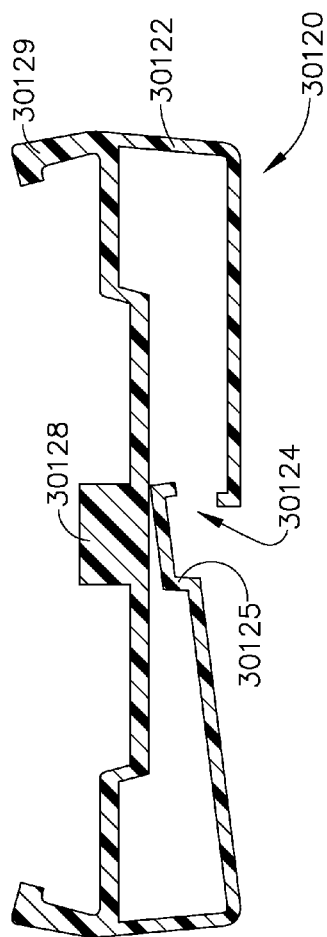


FIG. 220

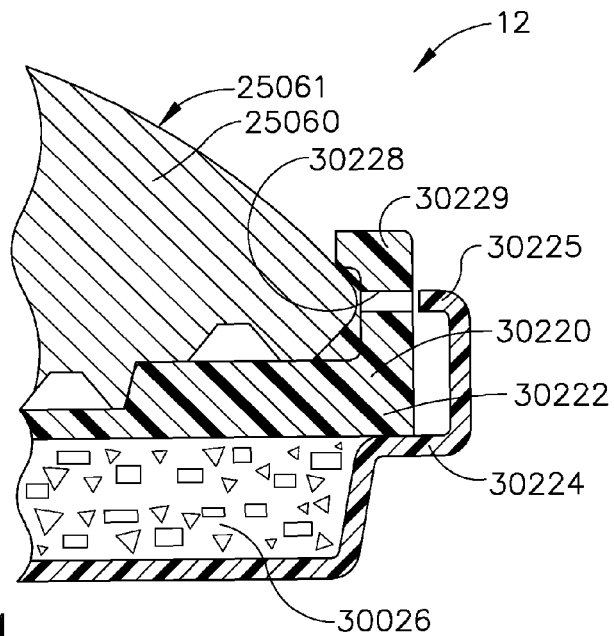


FIG. 221

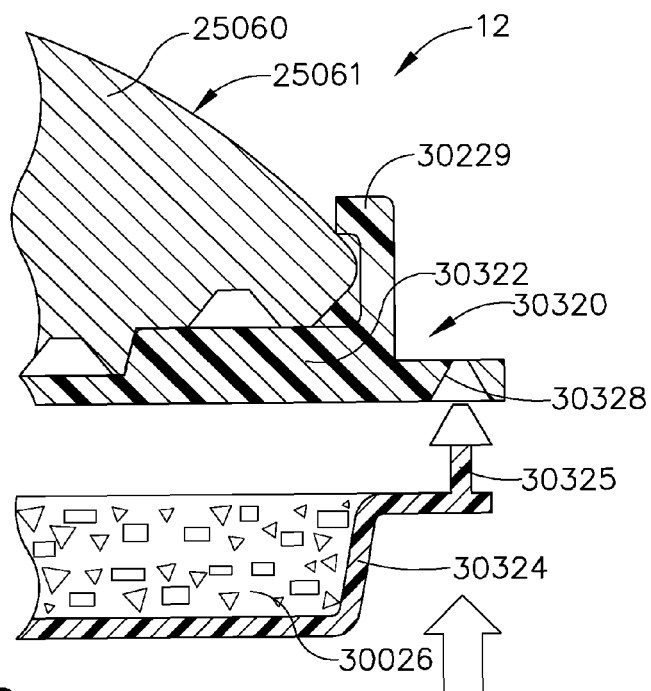


FIG. 222

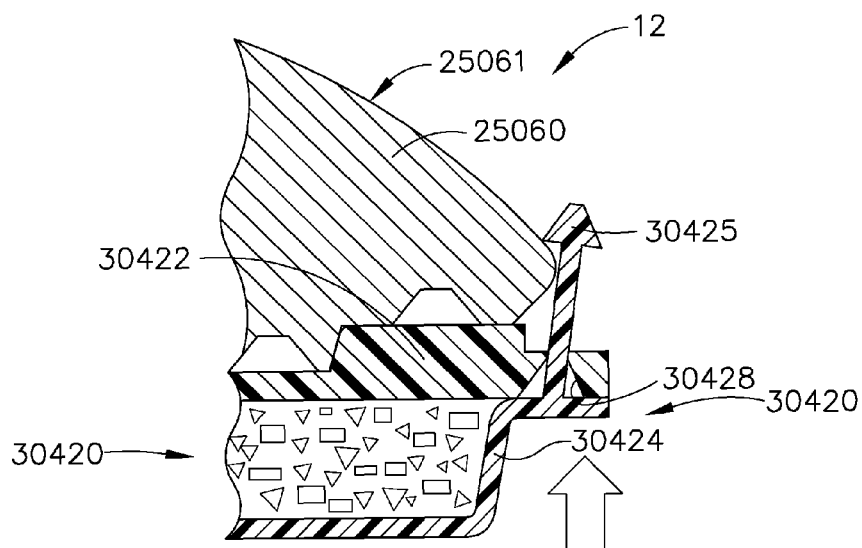


FIG. 223

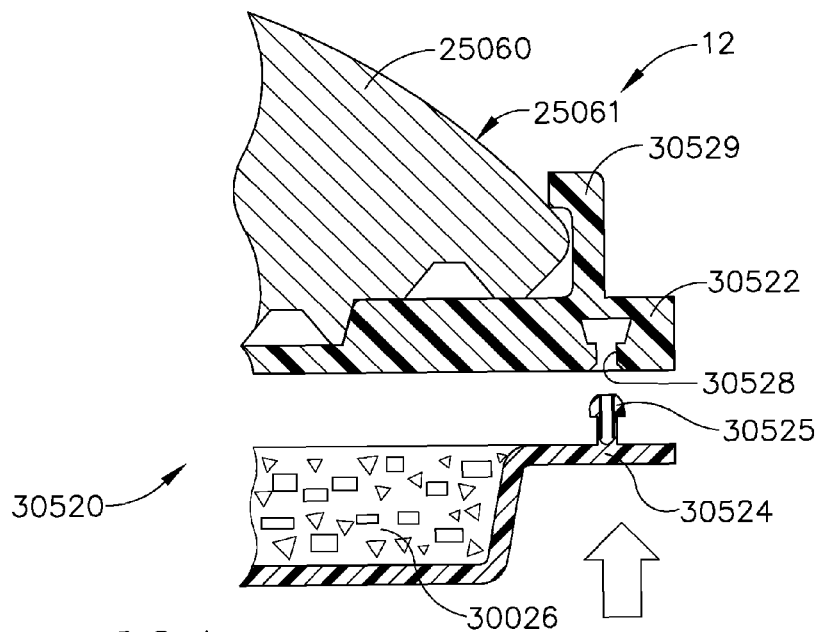


FIG. 224

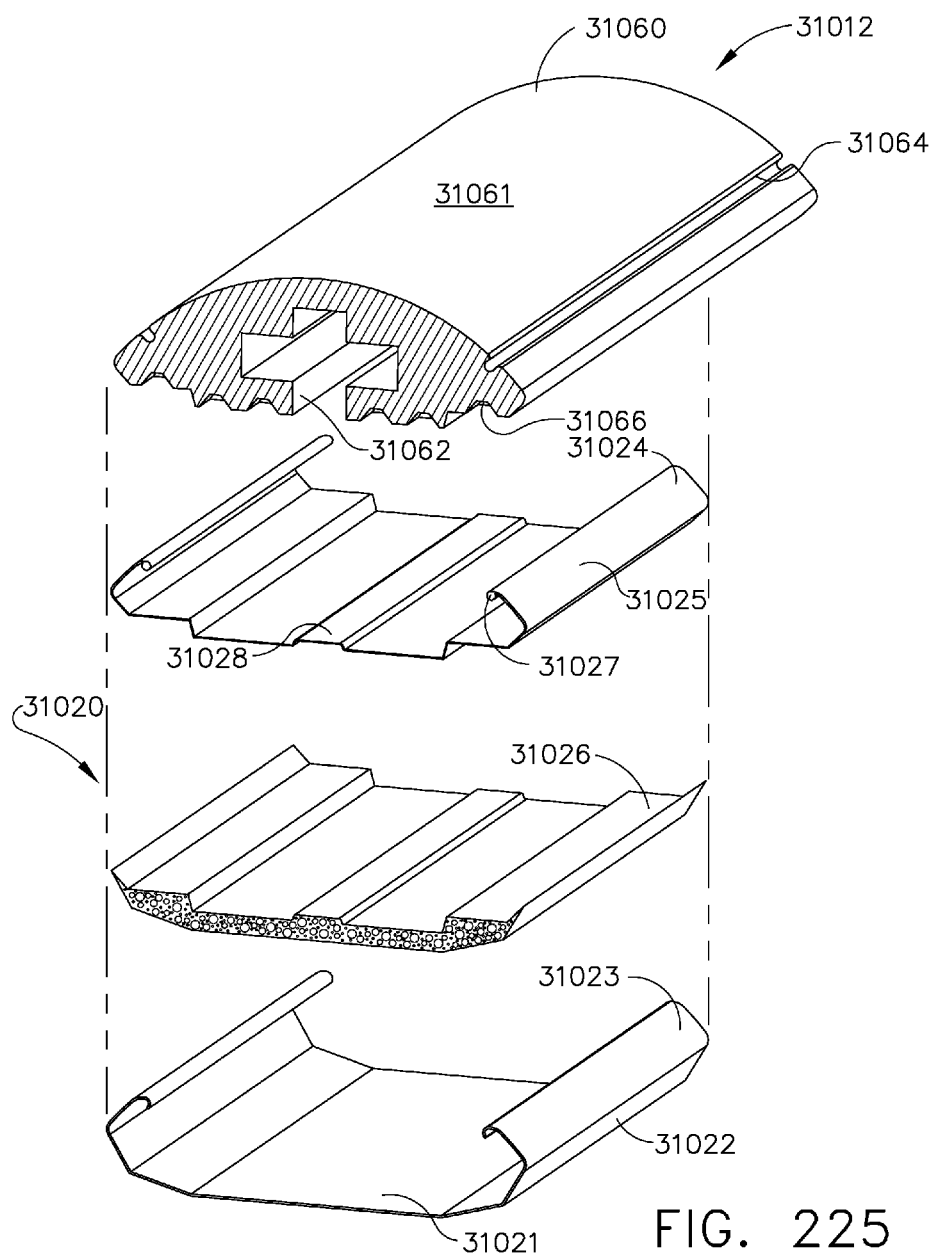


FIG. 225

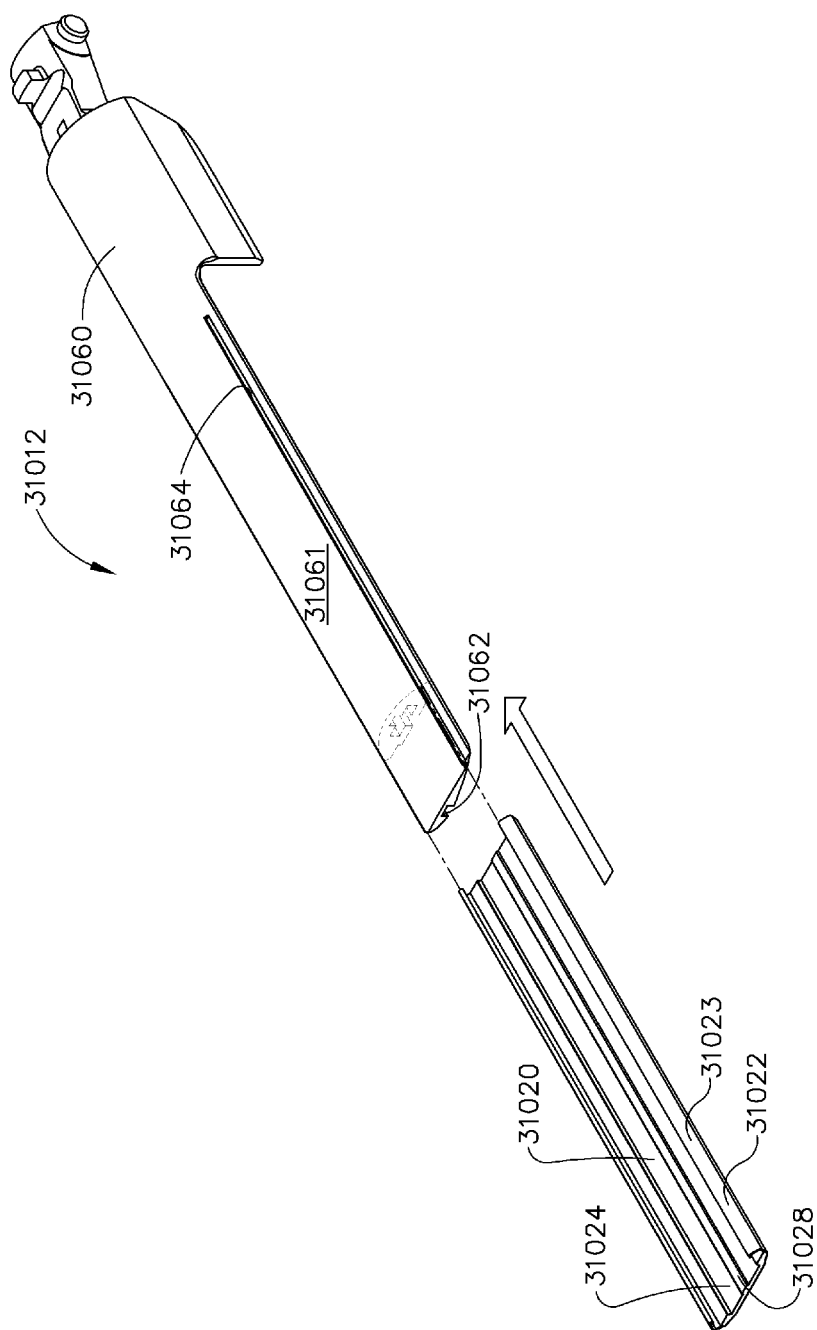


FIG. 226

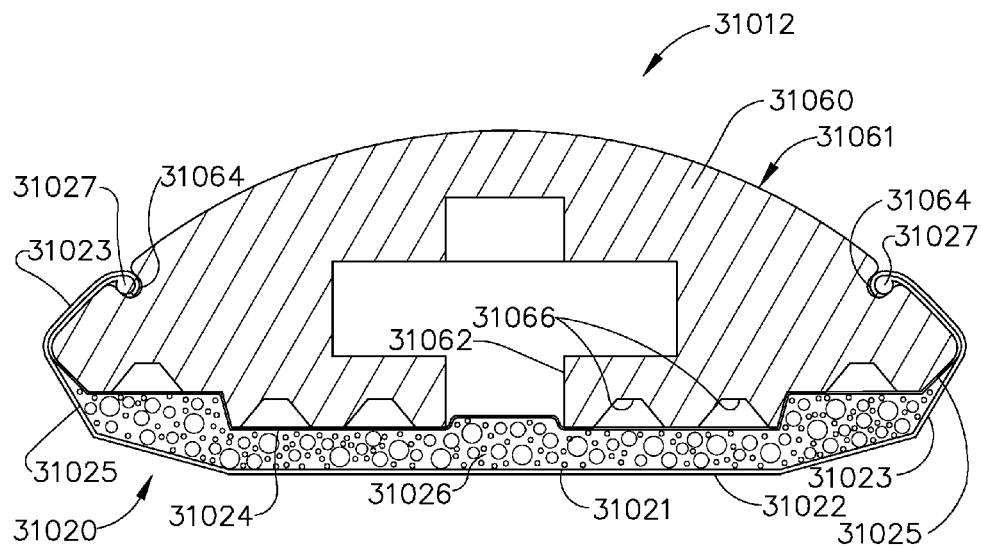


FIG. 227



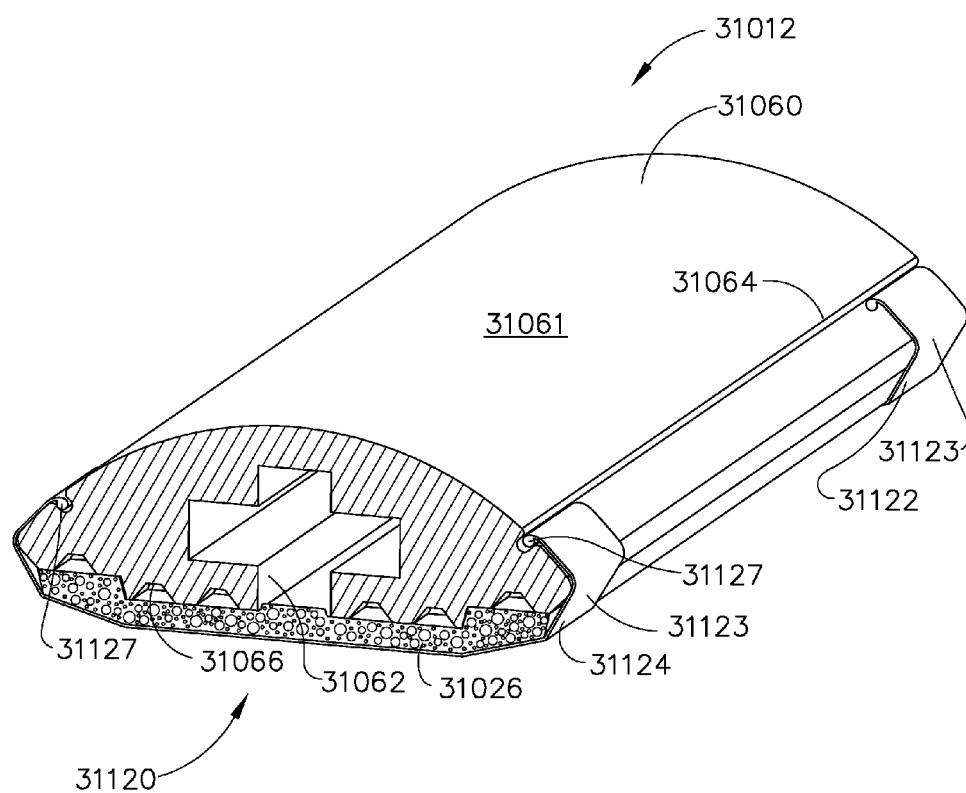


FIG. 228

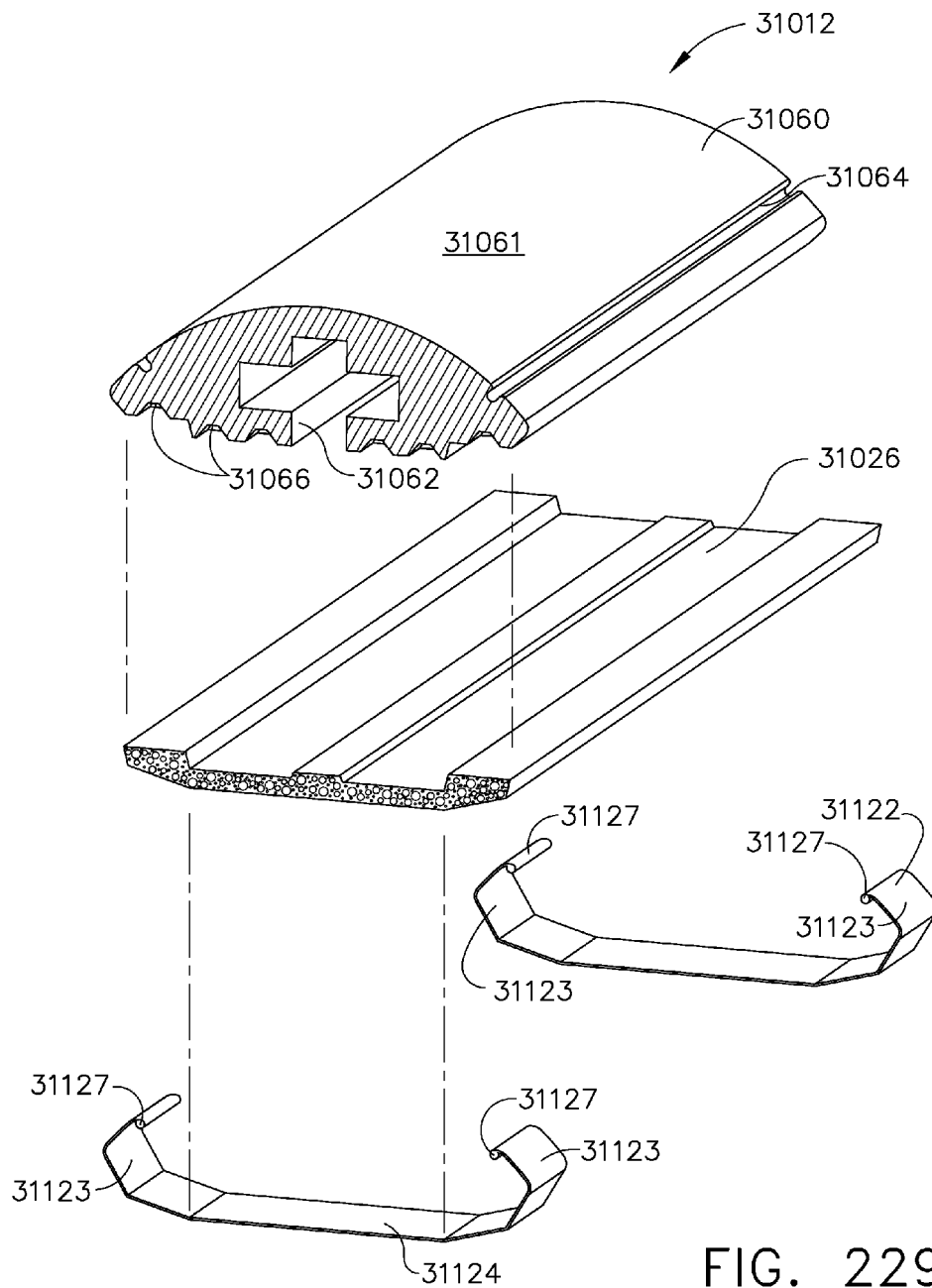


FIG. 229

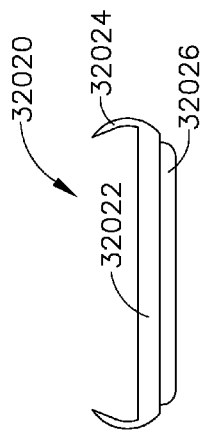


FIG. 230

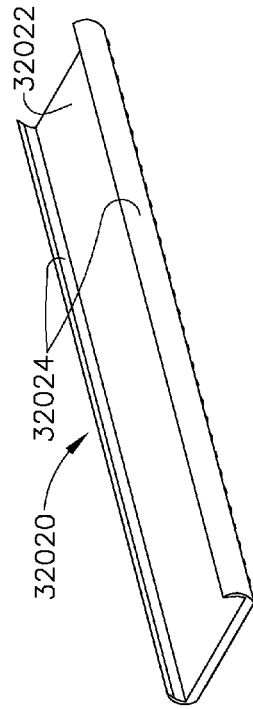


FIG. 231

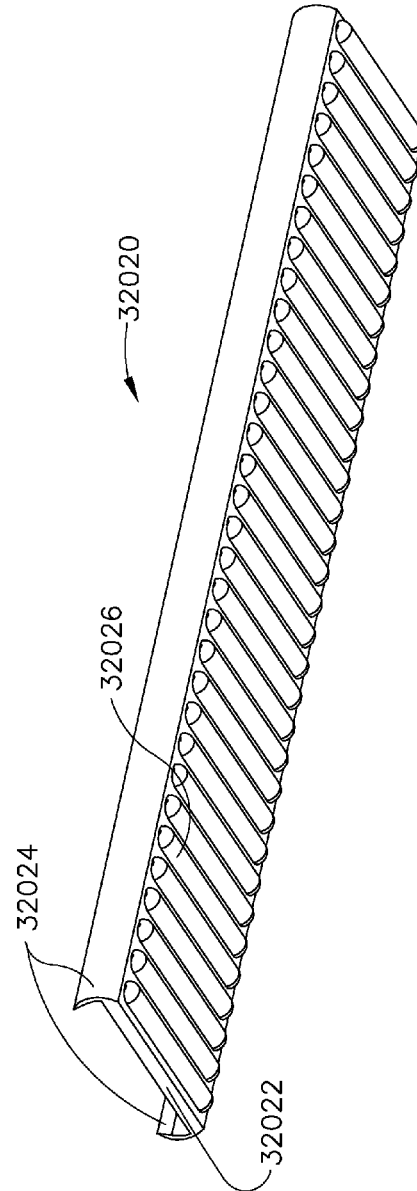


FIG. 232

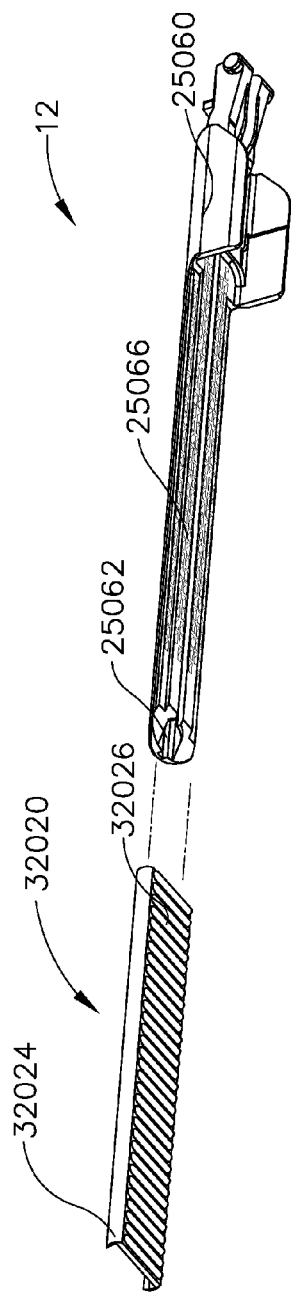


FIG. 233

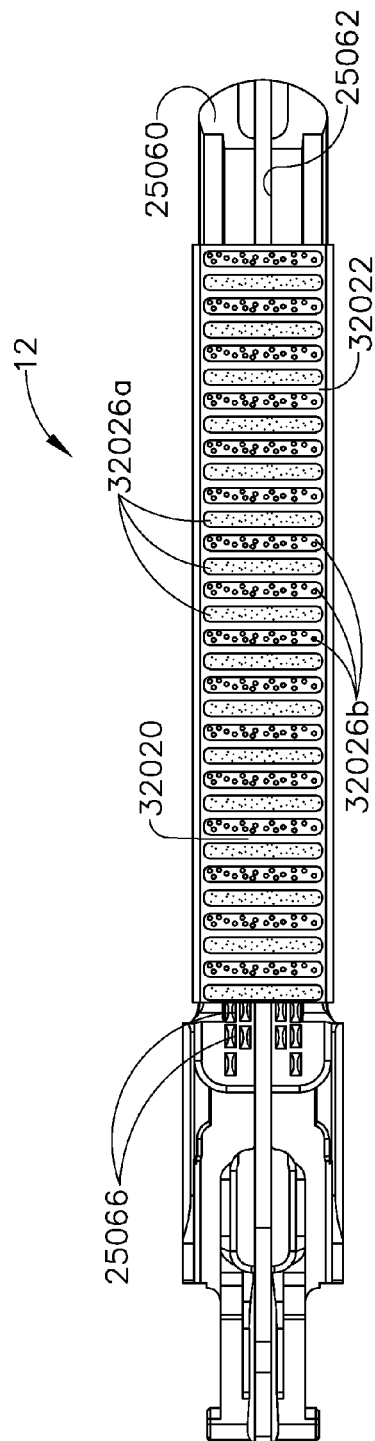


FIG. 234

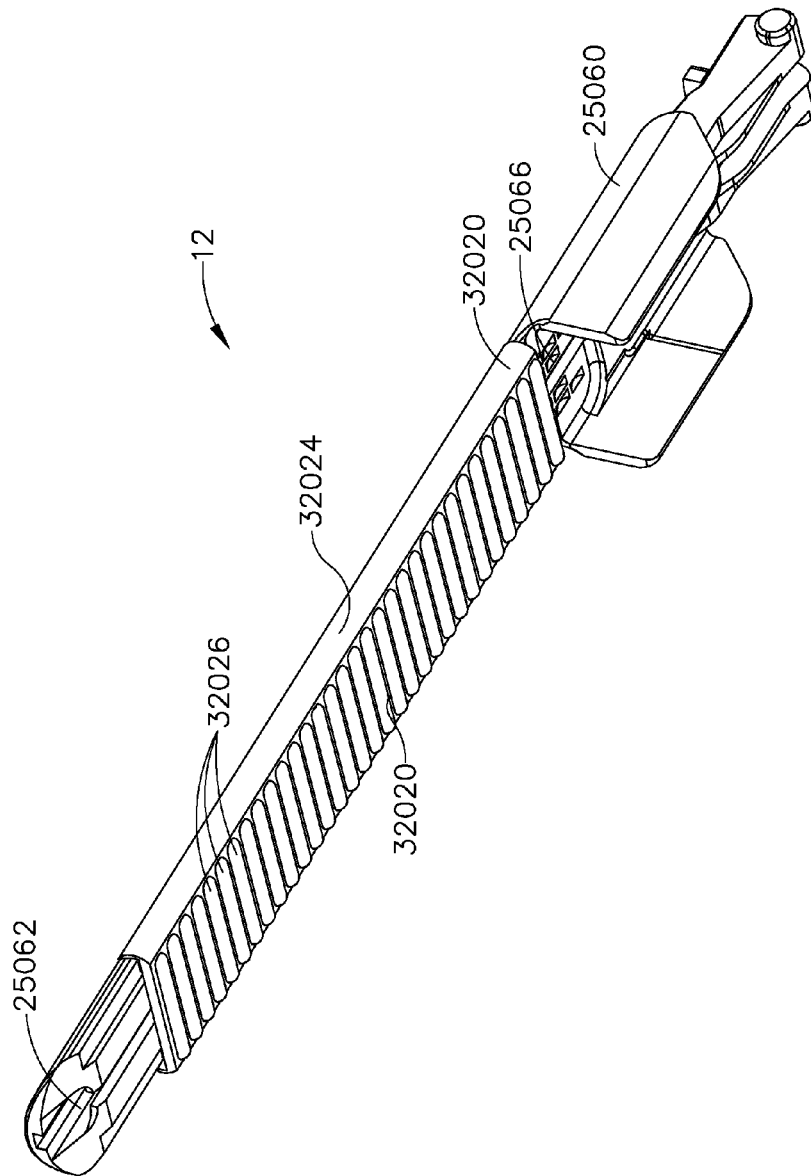


FIG. 235

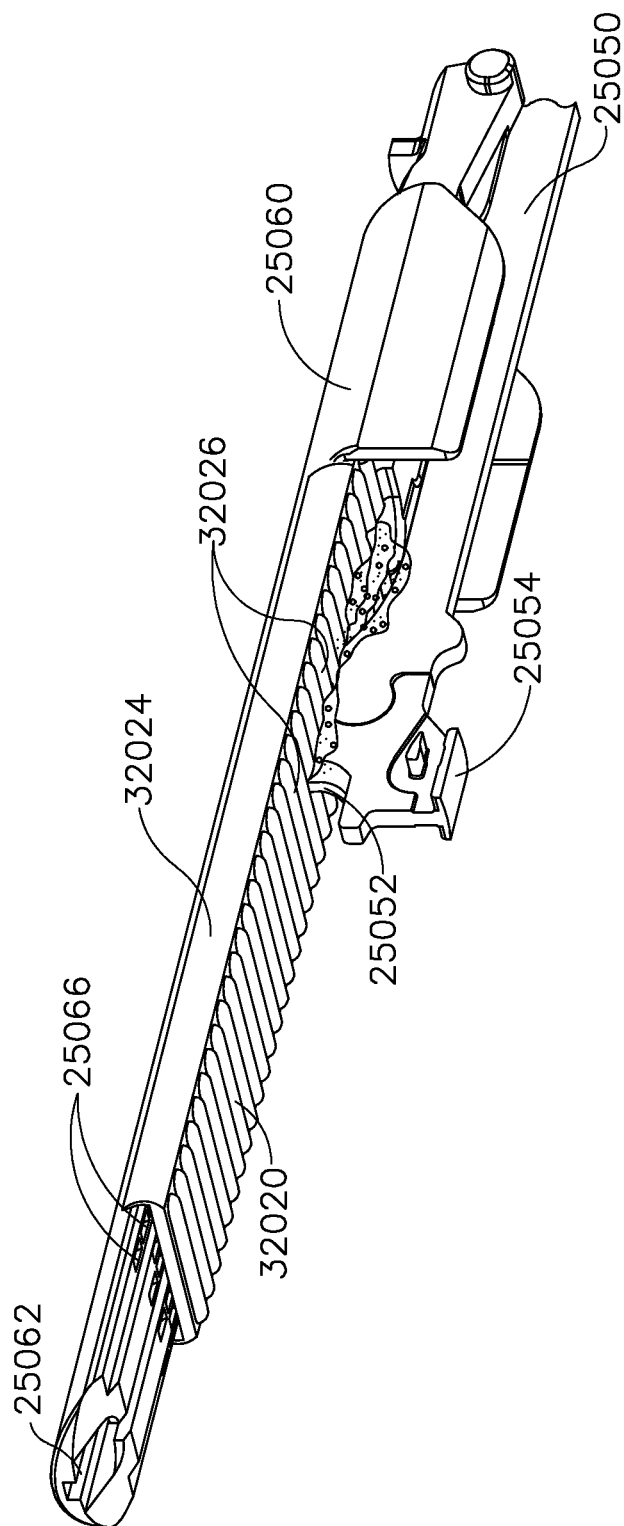


FIG. 236

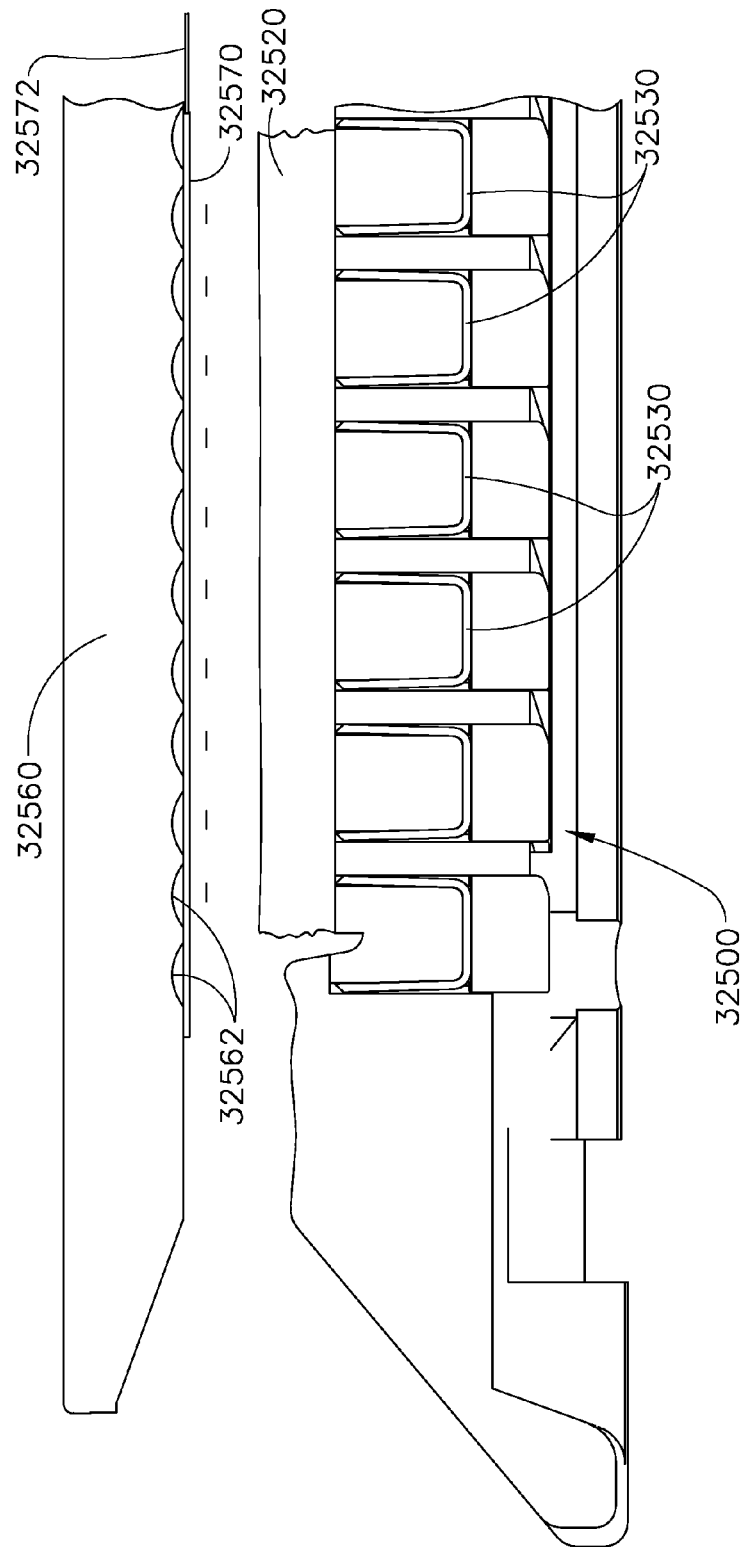


FIG. 237

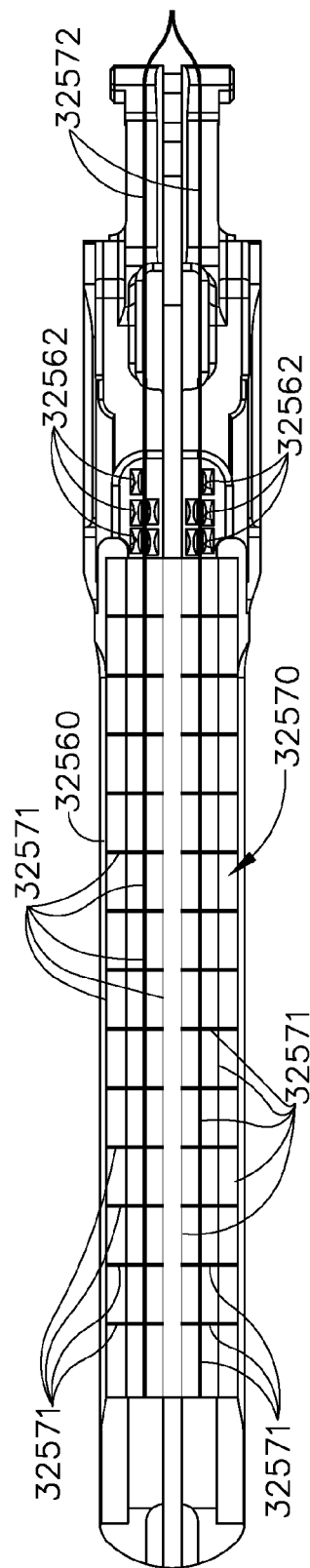


FIG. 238



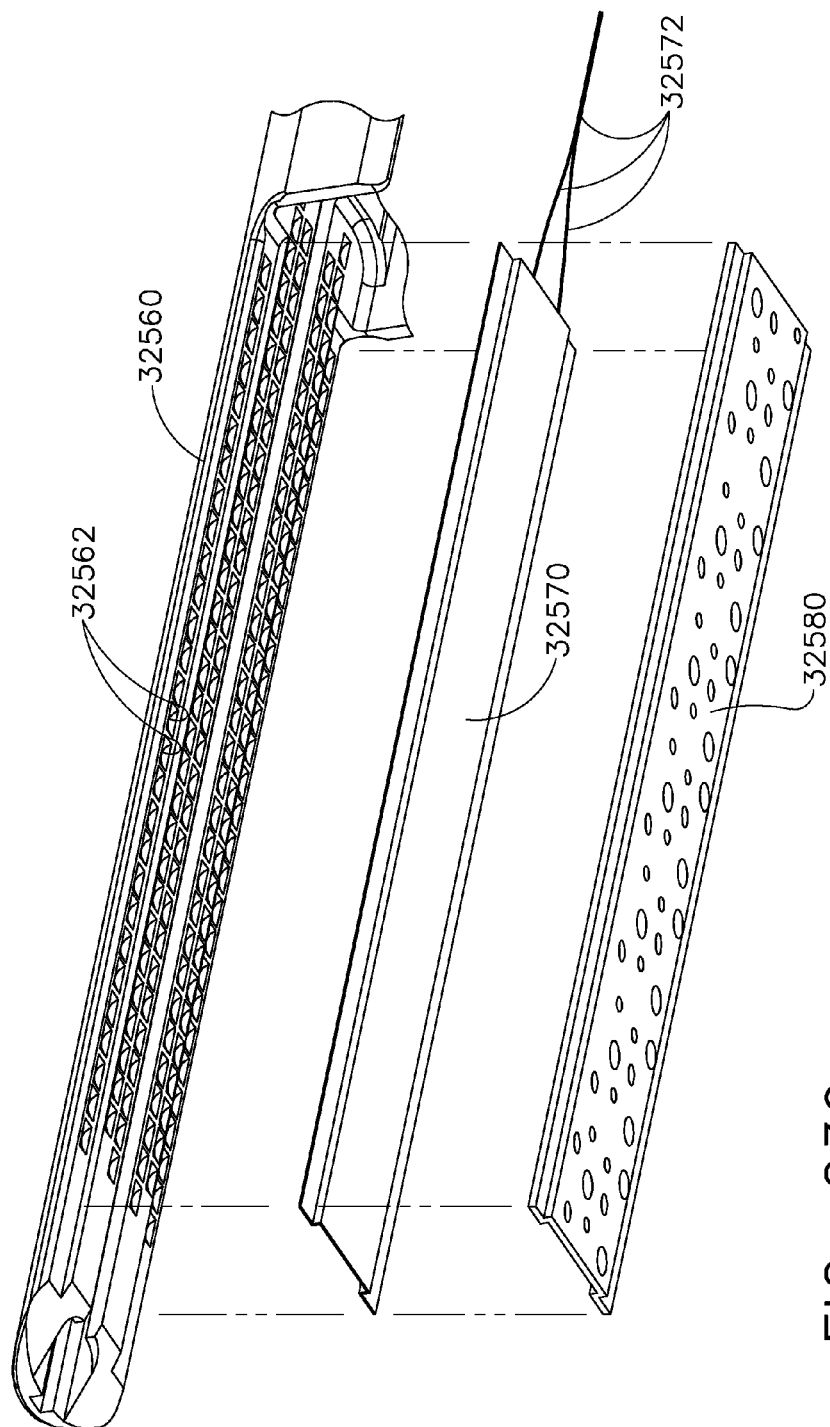


FIG. 239

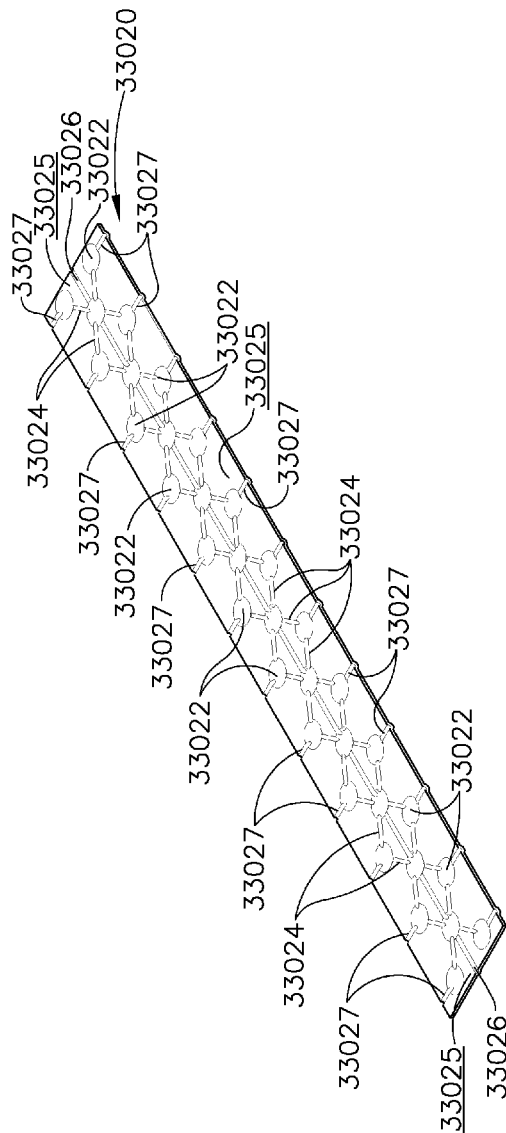


FIG. 240

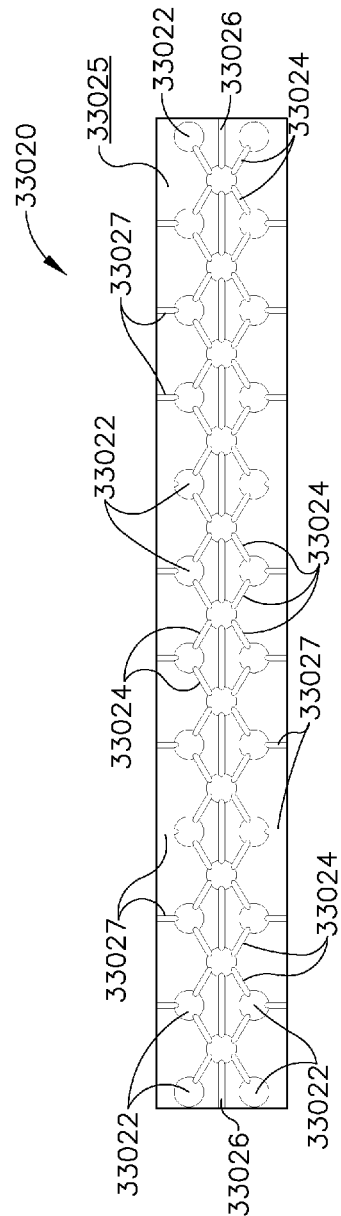


FIG. 241

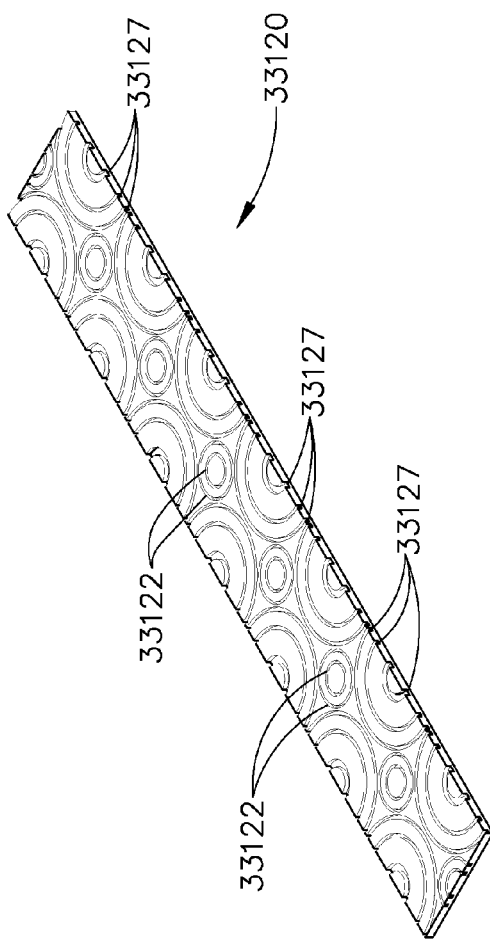


FIG. 240A

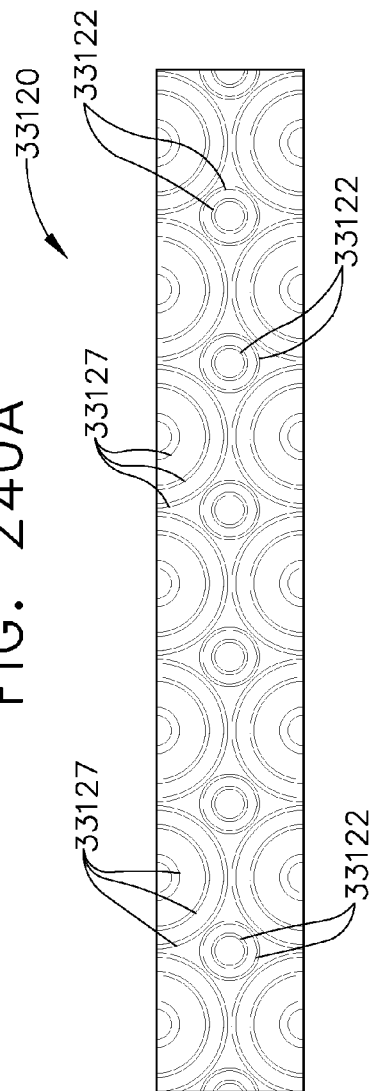


FIG. 241A

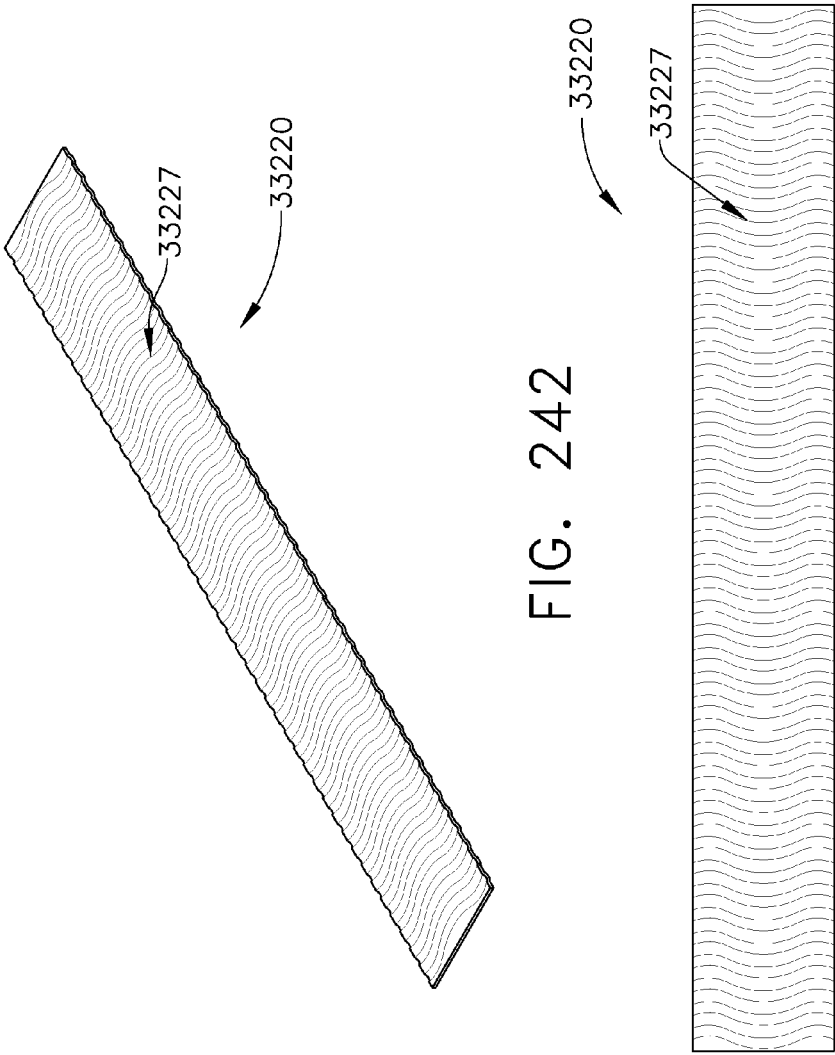


FIG. 242

FIG. 243

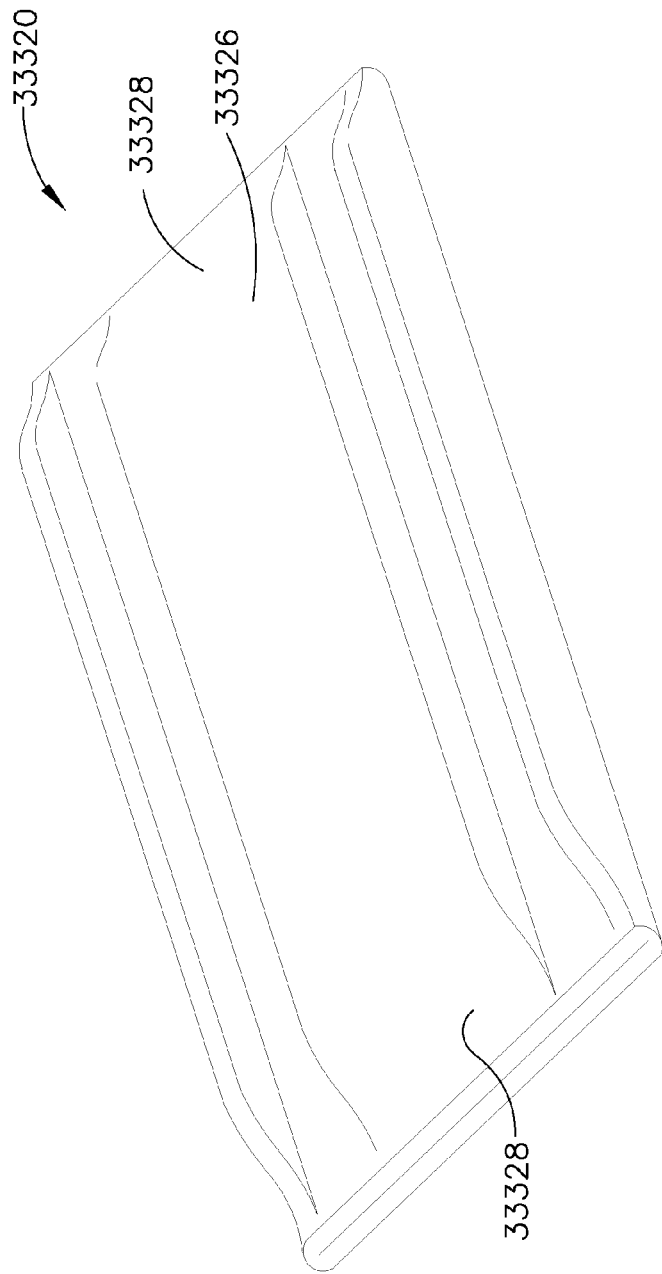


FIG. 244

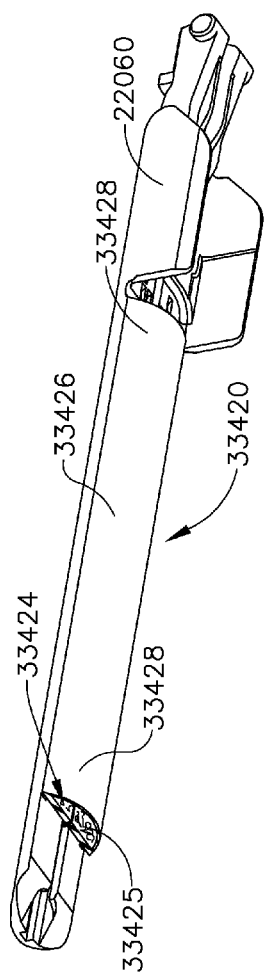


FIG. 245

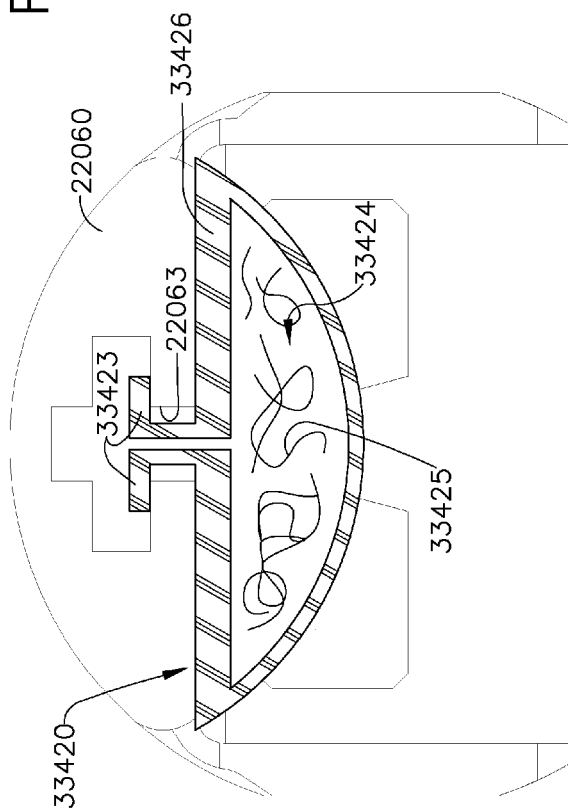


FIG. 246

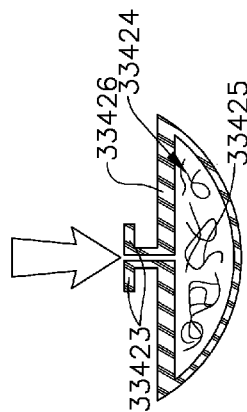


FIG. 247

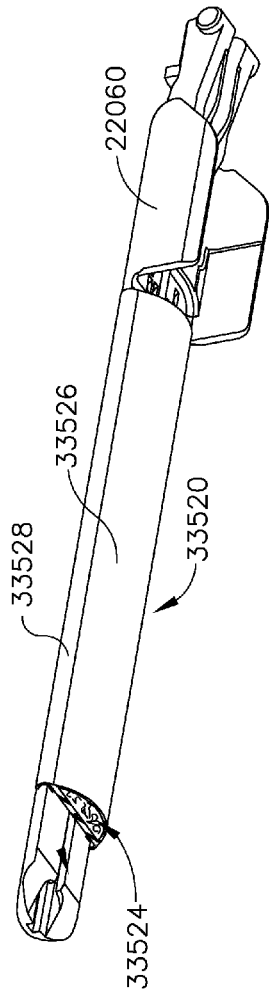


FIG. 248

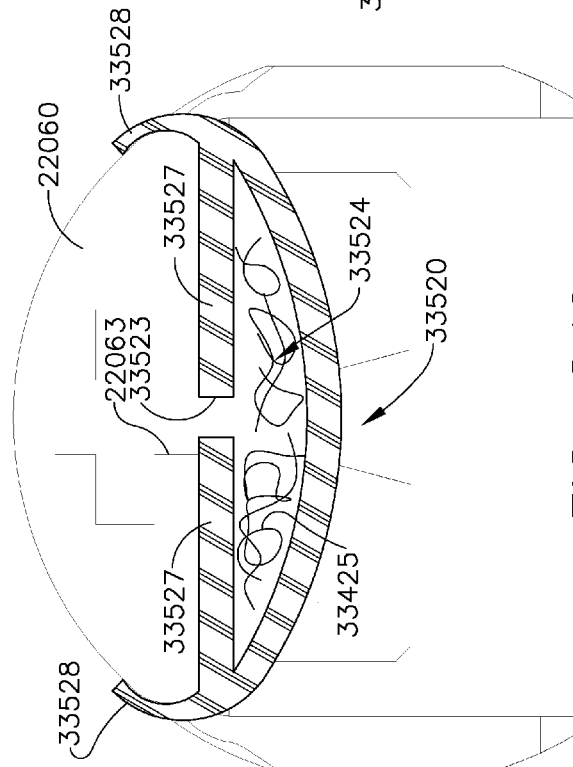


FIG. 249

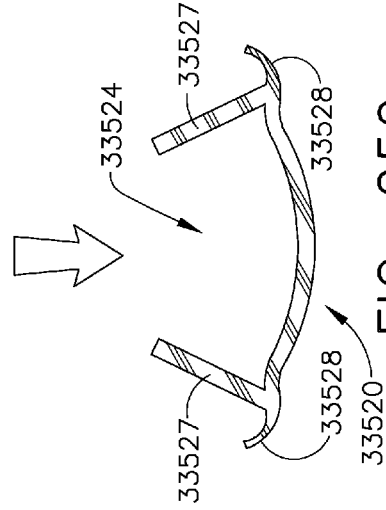


FIG. 250

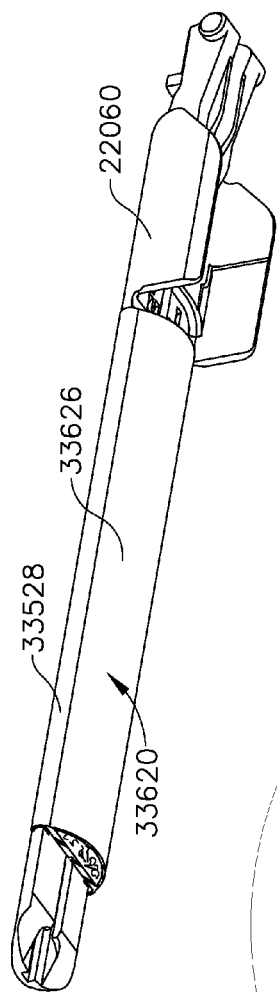


FIG. 251

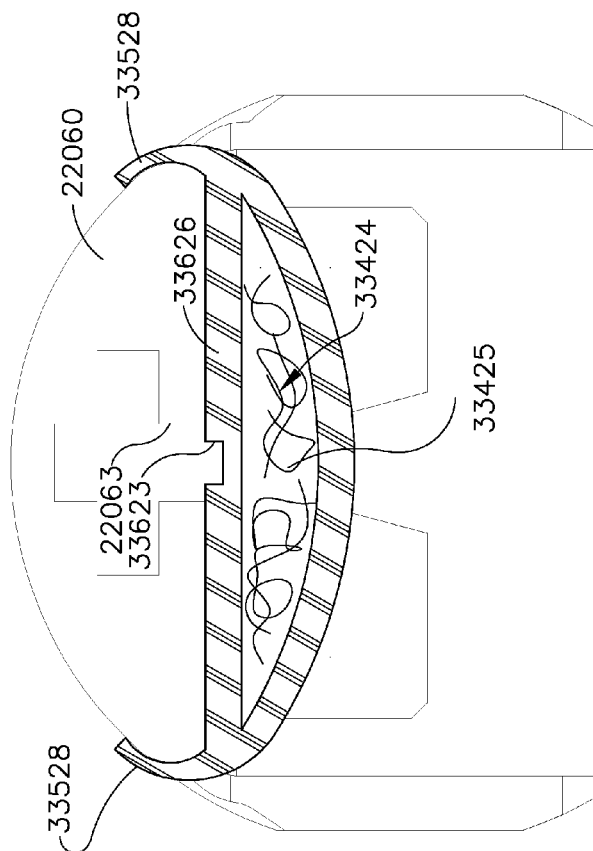


FIG. 252



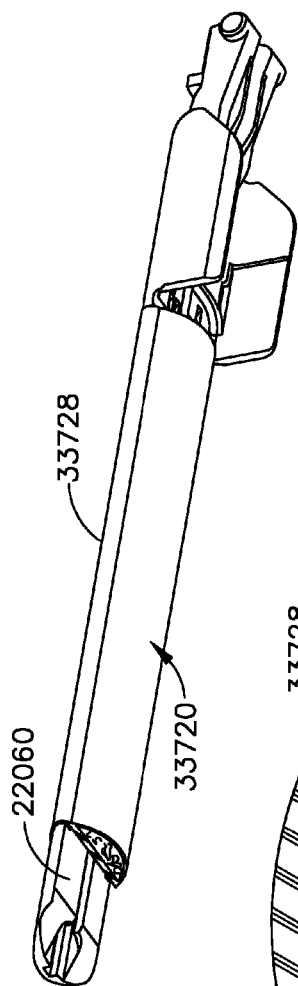


FIG. 253

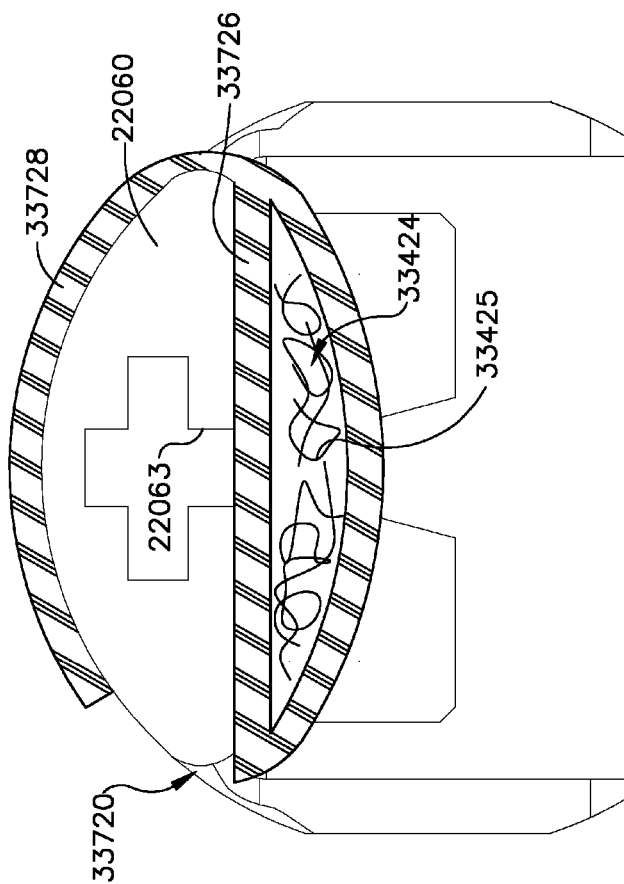


FIG. 254

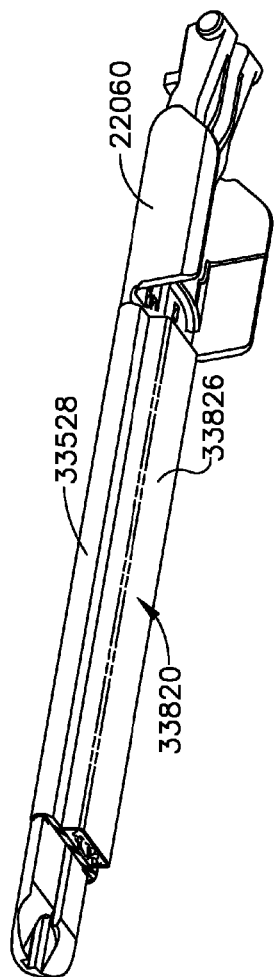


FIG. 255

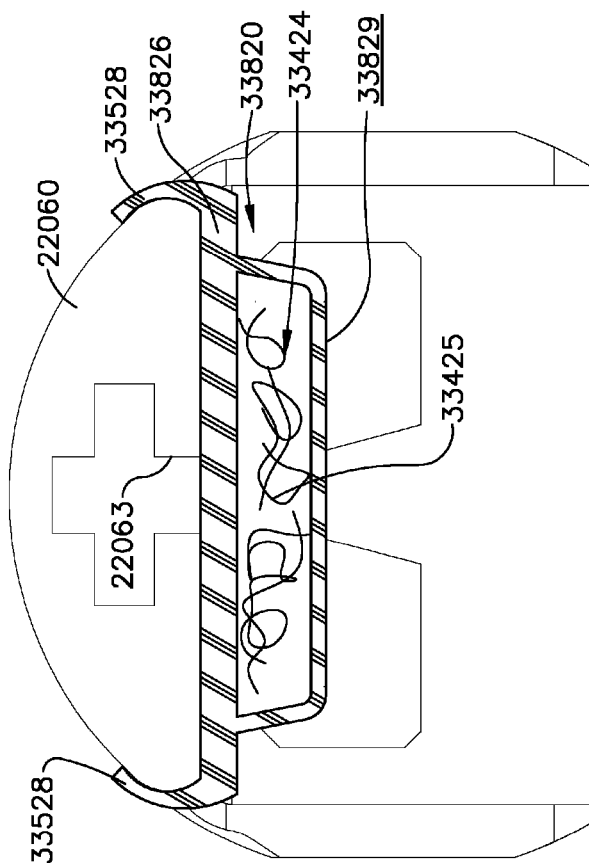


FIG. 256

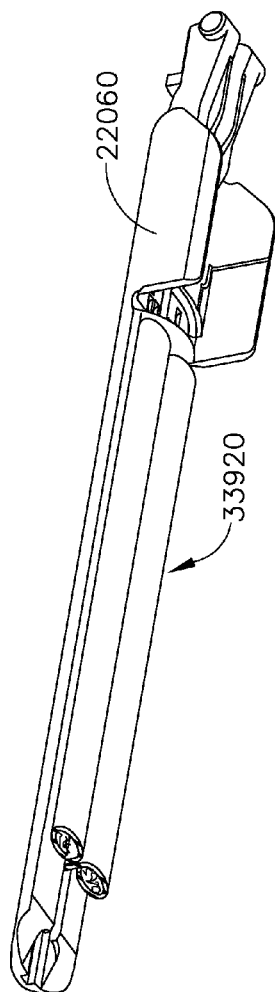


FIG. 257

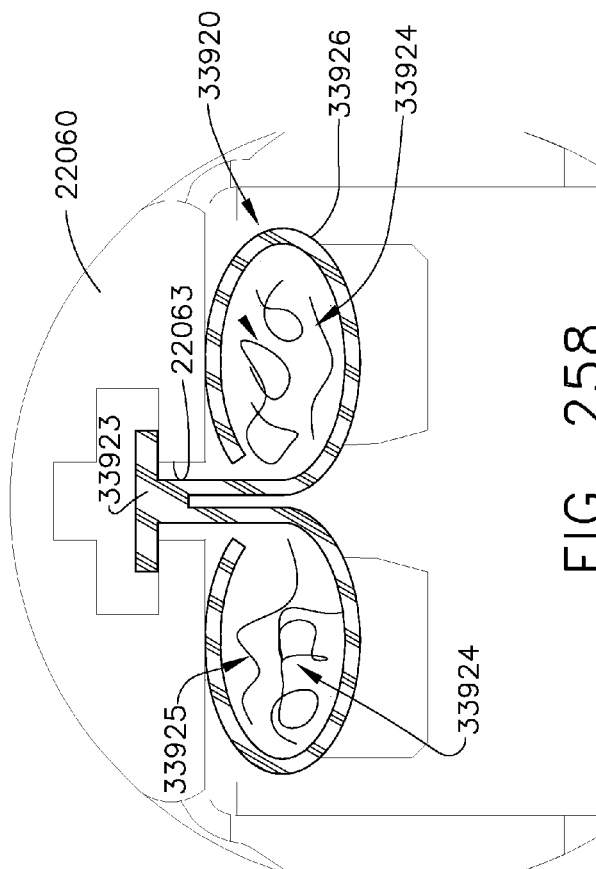


FIG. 258

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# TISSUE THICKNESS COMPENSATOR COMPRISING A PLURALITY OF MEDICAMENTS

## BACKGROUND

The present invention relates to surgical instruments and, in various embodiments, to surgical cutting and stapling instruments and staple cartridges therefor that are designed to cut and staple tissue.

## BRIEF DESCRIPTION OF THE DRAWINGS

The features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a cross-sectional view of a surgical instrument embodiment;

FIG. 1A is a perspective view of one embodiment of an implantable staple cartridge;

FIGS. 1B-1E illustrate portions of an end effector clamping and stapling tissue with an implantable staple cartridge;

FIG. 2 is a partial cross-sectional side view of another end effector coupled to a portion of a surgical instrument with the end effector supporting a surgical staple cartridge and with the anvil thereof in an open position;

FIG. 3 is another partial cross-sectional side view of the end effector of FIG. 2 in a closed position;

FIG. 4 is another partial cross-sectional side view of the end effector of FIGS. 2 and 3 as the knife bar is starting to advance through the end effector;

FIG. 5 is another partial cross-sectional side view of the end effector of FIGS. 2-4 with the knife bar partially advanced therethrough;

FIGS. 6A-6D diagram the deformation of a surgical staple positioned within a collapsible staple cartridge body in accordance with at least one embodiment;

FIG. 7A is a diagram illustrating a staple positioned in a crushable staple cartridge body;

FIG. 7B is a diagram illustrating the crushable staple cartridge body of FIG. 7A being crushed by an anvil;

FIG. 7C is a diagram illustrating the crushable staple cartridge body of FIG. 7A being further crushed by the anvil;

FIG. 7D is a diagram illustrating the staple of FIG. 7A in a fully formed configuration and the crushable staple cartridge of FIG. 7A in a fully crushed condition;

FIG. 8 is a top view of a staple cartridge in accordance with at least one embodiment comprising staples embedded in a collapsible staple cartridge body;

FIG. 9 is an elevational view of the staple cartridge of FIG. 8;

FIG. 10 is an exploded perspective view of an alternative embodiment of a compressible staple cartridge comprising staples therein and a system for driving the staples against an anvil;

FIG. 10A is a partial cut-away view of an alternative embodiment of the staple cartridge of FIG. 10;

FIG. 11 is a cross-sectional view of the staple cartridge of FIG. 10;

FIG. 12 is an elevational view of a sled configured to traverse the staple cartridge of FIG. 10 and move the staples to toward the anvil;

FIG. 13 is a diagram of a staple driver which can be lifted toward the anvil by the sled of FIG. 12;

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FIG. 14 is a perspective view of a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator for use with a surgical stapling instrument in accordance with at least one embodiment of the invention;

FIG. 15 is a partially exploded view of the staple cartridge of FIG. 14;

FIG. 16 is a fully exploded view of the staple cartridge of FIG. 14;

FIG. 17 is another exploded view of the staple cartridge of FIG. 14 without a warp covering the tissue thickness compensator;

FIG. 18 is a perspective view of a cartridge body, or support portion, of the staple cartridge of FIG. 14;

FIG. 19 is a top perspective view of a sled movable within the staple cartridge of FIG. 14 to deploy staples from the staple cartridge;

FIG. 20 is a bottom perspective view of the sled of FIG. 19;

FIG. 21 is an elevational view of the sled of FIG. 19;

FIG. 22 is a top perspective view of a driver configured to support one or more staples and to be lifted upwardly by the sled of FIG. 19 to eject the staples from the staple cartridge;

FIG. 23 is a bottom perspective view of the driver of FIG. 22;

FIG. 24 is a wrap configured to at least partially surround a compressible tissue thickness compensator of a staple cartridge;

FIG. 25 is a partial cut away view of a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator illustrated with staples being moved from an unfired position to a fired position during a first sequence;

FIG. 26 is an elevational view of the staple cartridge of FIG. 25;

FIG. 27 is a detail elevational view of the staple cartridge of FIG. 25;

FIG. 28 is a cross-sectional end view of the staple cartridge of FIG. 25;

FIG. 29 is a bottom view of the staple cartridge of FIG. 25;

FIG. 30 is a detail bottom view of the staple cartridge of FIG. 25;

FIG. 31 is a longitudinal cross-sectional view of an anvil in a closed position and a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator illustrated with staples being moved from an unfired position to a fired position during a first sequence;

FIG. 32 is another cross-sectional view of the anvil and the staple cartridge of FIG. 31 illustrating the anvil in an open position after the firing sequence has been completed;

FIG. 33 is a partial detail view of the staple cartridge of FIG. 31 illustrating the staples in an unfired position;

FIG. 34 is a cross-sectional elevational view of a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator illustrating the staples in an unfired position;

FIG. 35 is a detail view of the staple cartridge of FIG. 34;

FIG. 36 is an elevational view of an anvil in an open position and a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator illustrating the staples in an unfired position;

FIG. 37 is an elevational view of an anvil in a closed position and a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator illustrating the staples in an unfired position and tissue captured between the anvil and the tissue thickness compensator;

FIG. 38 is a detail view of the anvil and staple cartridge of FIG. 37;

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FIG. 39 is an elevational view of an anvil in a closed position and a staple cartridge comprising a rigid support portion and a compressible tissue thickness compensator illustrating the staples in an unfired position illustrating thicker tissue positioned between the anvil and the staple cartridge;

FIG. 40 is a detail view of the anvil and staple cartridge of FIG. 39;

FIG. 41 is an elevational view of the anvil and staple cartridge of FIG. 39 illustrating tissue having different thicknesses positioned between the anvil and the staple cartridge;

FIG. 42 is a detail view of the anvil and staple cartridge of FIG. 39 as illustrated in FIG. 41;

FIG. 43 is a diagram illustrating a tissue thickness compensator which is compensating for different tissue thickness captured within different staples;

FIG. 44 is a diagram illustrating a tissue thickness compensator applying a compressive pressure to one or more vessels that have been transected by a staple line;

FIG. 45 is a diagram illustrating a circumstance wherein one or more staples have been improperly formed;

FIG. 46 is a diagram illustrating a tissue thickness compensator which could compensate for improperly formed staples;

FIG. 47 is a diagram illustrating a tissue thickness compensator positioned in a region of tissue in which multiple staples lines have intersected;

FIG. 48 is a diagram illustrating tissue captured within a staple;

FIG. 49 is a diagram illustrating tissue and a tissue thickness compensator captured within a staple;

FIG. 50 is a diagram illustrating tissue captured within a staple;

FIG. 51 is a diagram illustrating thick tissue and a tissue thickness compensator captured within a staple;

FIG. 52 is a diagram illustrating thin tissue and a tissue thickness compensator captured within a staple;

FIG. 53 is a diagram illustrating tissue having an intermediate thickness and a tissue thickness compensator captured within a staple;

FIG. 54 is a diagram illustrating tissue having another intermediate thickness and a tissue thickness compensator captured within a staple;

FIG. 55 is a diagram illustrating thick tissue and a tissue thickness compensator captured within a staple;

FIG. 56 is a partial cross-sectional view of an end effector of a surgical stapling instrument illustrating a firing bar and staple-firing sled in a retracted, unfired position;

FIG. 57 is another partial cross-sectional view of the end effector of FIG. 56 illustrating the firing bar and the staple-firing sled in a partially advanced position;

FIG. 58 is a cross-sectional view of the end effector of FIG. 56 illustrating the firing bar in a fully advanced, or fired, position;

FIG. 59 is a cross-sectional view of the end effector of FIG. 56 illustrating the firing bar in a retracted position after being fired and the staple-firing sled left in its fully fired position;

FIG. 60 is a detail view of the firing bar in the retracted position of FIG. 59;

FIG. 61 is an exploded view of a retainer assembly including a retainer and two tissue thickness compensators in accordance with at least one embodiment;

FIG. 62 is a perspective view of the retainer assembly shown in FIG. 61;

FIG. 63 is a perspective view of an anvil with which the retainer assembly of FIG. 61 may be used;

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FIG. 64 is an illustration depicting the retainer assembly shown in FIG. 61 being inserted in an end effector of a surgical stapler which includes an anvil and a staple cartridge;

FIG. 65 is a side view of the retainer assembly shown in FIG. 61 engaged with the staple cartridge of FIG. 64;

FIG. 66 is a side view of the retainer assembly shown in FIG. 61 engaged with the staple cartridge and the anvil of FIG. 64 illustrating the anvil in a closed position;

FIG. 67 is a side view of the retainer assembly of FIG. 61 being removed from the end effector of FIG. 64;

FIG. 68 is a perspective view of a retainer;

FIG. 69 is a side view of the retainer of FIG. 68 with tissue thickness compensators attached to bottom and top surfaces thereof illustrating one of the tissue thickness compensators engaged with a staple cartridge in a surgical stapler comprising an anvil;

FIG. 70 is a side view illustrating the anvil of FIG. 69 in a closed position;

FIG. 71 is an exploded perspective view of a retainer and a tissue thickness compensator in accordance with at least one embodiment;

FIG. 72 is an exploded perspective view of the tissue thickness compensator of FIG. 71 and an anvil of a surgical stapler;

FIG. 73 is an exploded top perspective view of a retainer and a tissue thickness compensator in accordance with at least one embodiment;

FIG. 74 is an exploded bottom perspective view of the retainer and tissue thickness compensator of FIG. 73;

FIG. 75 is a top perspective view of the retainer and tissue thickness compensator of FIG. 73 engaged with a surgical stapler;

FIG. 76 is a bottom perspective view of the retainer and tissue thickness compensator of FIG. 73 engaged with the surgical stapler of FIG. 75;

FIG. 77 is a side view of the retainer and tissue thickness compensator of FIG. 73 engaged with the surgical stapler of FIG. 75;

FIG. 78 is a bottom perspective view of the retainer and tissue thickness compensator of FIG. 73 illustrating the tissue thickness compensator attached to the anvil of the surgical stapler of FIG. 75;

FIG. 79 is a top perspective view of the retainer and tissue thickness compensator of FIG. 73 illustrating the tissue thickness compensator attached to the anvil of FIG. 78;

FIG. 80 is a side view of the tissue thickness compensator of FIG. 73 attached to the anvil of FIG. 78;

FIG. 81 is a cross-sectional view of the retainer and tissue thickness compensator of FIGS. 73 and 74 attached to a staple cartridge and channel of a surgical stapler;

FIG. 82 is a cross-sectional view of the retainer and tissue thickness compensator of FIGS. 73 and 74 attached to the staple cartridge and channel of the surgical stapler of FIG. 81 illustrating an anvil of the surgical stapler engaged with the tissue thickness compensator;

FIG. 83 is a cross-sectional view of the tissue thickness compensator of FIG. 73 attached to the anvil of the surgical stapler and being moved away from the retainer;

FIG. 84 is a side cross-sectional view of a retainer assembly comprising a retainer, tissue thickness compensators mounted on first and second surfaces of the retainer, and connectors passing through holes in the retainer in accordance with at least one embodiment;

FIG. 85 is a perspective view of the retainer assembly of FIG. 84 illustrated with a portion of a tissue thickness compensator removed for the purposes of illustration;

FIG. 86 is a side view of the retainer assembly of FIG. 84 engaged with a surgical stapler comprising an anvil illustrated in an open position;

FIG. 87 is a side view of the retainer assembly of FIG. 84 and the anvil of FIG. 86 illustrated in a closed position;

FIG. 88 is a side view of the retainer assembly of FIG. 84 illustrating the retainer being removed from between the tissue thickness compensators of the retainer assembly;

FIG. 89 is a side view of the retainer removed from the tissue thickness compensators of FIG. 84;

FIG. 90 is a perspective view of a retainer configured to engage an anvil of a surgical stapler in accordance with at least one embodiment;

FIG. 91 is a top view of the retainer of FIG. 90;

FIG. 92 is a side view of the retainer of FIG. 90;

FIG. 93 is a bottom view of the retainer of FIG. 90;

FIG. 94 illustrates a retainer assembly comprising the retainer of FIG. 90 and a tissue thickness compensator being attached to a staple cartridge for a surgical stapler;

FIG. 95 illustrates the retainer assembly and staple cartridge of FIG. 94 engaging an anvil of an end effector of a surgical stapler;

FIG. 96 illustrates the retainer assembly and staple cartridge of FIG. 94 engaging the anvil of the end effector of the surgical stapler of FIG. 95;

FIG. 97 illustrates the retainer assembly and staple cartridge of FIG. 94 engaged on the anvil of the surgical stapler of FIG. 95;

FIG. 98 illustrates the retainer assembly and staple cartridge of FIG. 94 engaged on the anvil of the surgical stapler of FIG. 95 and the anvil being moved into a closed position;

FIG. 99 illustrates the anvil of the surgical stapler of FIG. 95 in an open position with the tissue thickness compensator attached thereto and the retainer engaged with the staple cartridge channel of the surgical stapler;

FIG. 100 illustrates the retainer of FIG. 94 engaged with the staple cartridge channel of the surgical stapler of FIG. 95 and the anvil in an open position;

FIG. 101 is a cross-sectional view of a retainer including a tissue thickness compensator comprising protrusions or wings configured to engage an anvil of a surgical stapler;

FIG. 102 is a cross-sectional view of a retainer including a tissue thickness compensator comprising a sock configured to engage an anvil of a surgical stapler;

FIG. 103 is a perspective view of a retainer that includes two plates connected by a hinge according to at least one embodiment;

FIG. 104 is a side view of the retainer of FIG. 103;

FIG. 105 is a rear perspective view of an embodiment of an insertion tool configured for use with the retainer of FIG. 103;

FIG. 106 is a top perspective view of the insertion tool of FIG. 105;

FIG. 107 is a rear perspective view of the insertion tool of FIG. 105 with a portion of the insertion tool removed for purposes of illustration;

FIG. 108 is a side view of the insertion tool of FIG. 105 with a portion of the insertion tool removed for purposes of illustration;

FIG. 109 is a top view of the insertion tool of FIG. 105;

FIG. 110 is a perspective view of a retainer assembly comprising the retainer of FIG. 103, a tissue thickness compensator positioned on the retainer, a staple cartridge positioned on the retainer, and the insertion tool of FIG. 105 engaged with the retainer, wherein a portion of the insertion tool is removed for purposes of illustration;

FIG. 111 is a side view of a retainer assembly comprising the retainer of FIG. 103, a tissue thickness compensator posi-

tioned on the retainer, and the insertion tool of FIG. 105 engaged with the retainer, wherein a portion of the insertion tool is removed for purposes of illustration;

FIG. 112 illustrates the retainer assembly of FIG. 110 being inserted into a surgical instrument comprising an anvil and a staple cartridge channel, wherein a portion of the insertion tool is removed for the purposes of illustration;

FIG. 113 illustrates the retainer assembly of FIG. 110 being inserted into a surgical instrument comprising an anvil and a staple cartridge channel, wherein a portion of the insertion tool is removed for the purposes of illustration;

FIG. 114 illustrates the insertion tool of FIG. 105 being moved relative to the retainer to engage the staple cartridge in the staple cartridge channel and to engage the tissue thickness compensator with the anvil, wherein a portion of the insertion tool is removed for the purposes of illustration;

FIG. 115 illustrates the insertion tool of FIG. 105 being moved relative to the retainer to disengage the retainer from the tissue thickness compensator and from the staple cartridge, wherein a portion of the insertion tool is removed for the purposes of illustration;

FIG. 116 is a cross-sectional view of a tissue thickness compensator attached to an anvil of a surgical stapling instrument in accordance with at least one embodiment;

FIG. 117 is a diagram illustrating deformed staples at least partially capturing the tissue thickness compensator of FIG. 116 therein;

FIG. 118 is a cross-sectional view of an end effector of a surgical stapling instrument including a staple cartridge comprising a first tissue thickness compensator and an anvil comprising a second tissue thickness compensator in accordance with at least one embodiment;

FIG. 119 is a cross-sectional view of the end effector of FIG. 118 illustrating staples from the staple cartridge moved from an unfired position to a fired position;

FIG. 120 is a perspective view of a tissue thickness compensator attached to an anvil of an end effector wherein the tissue thickness compensator comprises a plurality of capsules in accordance with at least one embodiment;

FIG. 120A is a partial perspective view of the tissue thickness compensator of FIG. 120;

FIG. 121 is a cross-sectional view of staples being moved from an unfired position to a fired position to puncture the capsules of the tissue thickness compensator of FIG. 120;

FIG. 122 is an exploded view of an anvil and a tissue thickness compensator in accordance with at least one embodiment;

FIG. 123 is a cross-sectional view of an anvil comprising a plurality of staple forming pockets and a tissue thickness compensator comprising a plurality of capsules aligned with the forming pockets in accordance with at least one embodiment;

FIG. 124 is a detail view of the capsules of the tissue thickness compensator of FIG. 123;

FIG. 125 is a diagram illustrating the anvil and the tissue thickness compensator of FIG. 123 positioned relative to tissue which is to be stapled by staples from a staple cartridge positioned on the opposite side of the tissue;

FIG. 126 is a diagram illustrating the anvil of FIG. 123 moved toward the staple cartridge of FIG. 125 and staples partially fired from the staple cartridge;

FIG. 127 is a diagram illustrating the staples of FIG. 126 in a fully-fired configuration and the capsules of the tissue thickness compensator of FIG. 123 in a ruptured state;

FIG. 128 is a diagram illustrating a staple of FIG. 126 in a misfired condition;

FIG. 129 is a diagram illustrating the staples of FIG. 126 in a fully-fired configuration and the tissue thickness compensator of FIG. 123 in at least partially transected condition;

FIG. 130 is a cross-sectional perspective view of an alternative embodiment of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 131 is a perspective view of an alternative embodiment of a tissue thickness compensator comprising a plurality of capsules aligned with a cutting member of a surgical stapling instrument;

FIG. 132 is a detail view of the capsules of FIG. 131;

FIG. 133 is a cross-sectional view of the tissue thickness compensator of FIG. 131 comprising a plurality of capsules aligned with a knife slot of an anvil of a surgical stapling instrument;

FIGS. 134 and 135 illustrate an alternative embodiment of a tissue thickness compensator being attached to an anvil;

FIG. 136 is a cross-sectional exploded view of an anvil and a compensator in accordance with at least one embodiment;

FIG. 137 illustrates the compensator of FIG. 136 attached to the anvil;

FIG. 138 is a partial perspective view of a tissue thickness compensator and a cutting member incising the tissue thickness compensator in accordance with at least one embodiment;

FIG. 139 is a partial cross-sectional view of an alternative embodiment of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 140 is a partial cross-sectional view of another alternative embodiment of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 141 is an illustration depicting a tissue thickness compensator comprising a plurality of irregular and/or asymmetrical cavities in accordance with various embodiments;

FIG. 142 is a partial cut-away view of a tissue thickness compensator attached to an anvil of a surgical stapling instrument in accordance with at least one embodiment;

FIG. 143 is a perspective view of a seamless extruded casing, or outer tube, of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 144 is a perspective view of another seamless extruded casing, or outer tube, of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 145 is a perspective view of oxidized regenerated cellulose fibers;

FIG. 146 is a perspective view of oxidized regenerated cellulose fibers which are shorter than the fibers of FIG. 145;

FIG. 147 is a diagram illustrating the fibers of FIG. 145 being woven into a strand utilizing the fibers of FIG. 146;

FIG. 148 depicts the strand of FIG. 147 being fluffed and at least partially cut;

FIG. 149 depicts a grasper inserted through a casing, or outer tube, of a tissue thickness compensator and positioned to grasp the strand of FIG. 147;

FIG. 150 illustrates the grasper of FIG. 149 being withdrawn from the casing and the strand of FIG. 147 being pulled through the casing;

FIG. 151 illustrates the casing and the strand of FIG. 150 being segmented;

FIG. 152 illustrates the ends of the casing being heat-welded and/or sealed;

FIG. 153 illustrates a process for creating a tissue thickness compensator without lateral seams;

FIG. 154 illustrates an anvil of a surgical stapling instrument and a plurality of compensators which can be selectively attached to the anvil, wherein each of the compensators comprises an array of capillary channels;

FIG. 155 is a plan view of a compensator configured to be attached to an anvil;

FIG. 156 is a detail view of a portion of the compensator of FIG. 155;

FIG. 157 is a perspective view of an end effector of a surgical stapling instrument;

FIG. 158 is another perspective view of the end effector of FIG. 157 illustrating a fluid being placed on a tissue thickness compensator of the end effector;

FIG. 159 is another perspective view of the end effector of FIG. 159 illustrating a compensator attached to an anvil of the end effector;

FIG. 160 is a detail view of an array of capillary channels on the compensator of FIG. 159;

FIG. 161 is an exploded view of a compensator comprising a plurality of layers in accordance with at least one embodiment;

FIG. 162 is an exploded view of a compensator and an anvil of a surgical stapling instrument in accordance with at least one embodiment;

FIG. 163 is a partial cross-sectional view of the compensator and the anvil of FIG. 162;

FIG. 164 is an exploded view of a compensator comprising a cellular ingrowth matrix in accordance with at least one embodiment;

FIG. 165 is a perspective view of the compensator of FIG. 164;

FIG. 166 is a perspective view of a fibrous layer of material for a compensator;

FIG. 167 is a perspective view of a plurality of fibrous layers stacked on one another in accordance with at least one embodiment;

FIG. 168 is a perspective view of another plurality of fibrous layers stacked on one another in accordance with at least one embodiment;

FIG. 169 is a perspective view of a fibrous layer of material for a compensator;

FIG. 170 is a perspective view of a plurality of fibrous layers stacked on one another wherein the fibers are arranged in different directions in accordance with at least one embodiment;

FIG. 171 is a perspective view of another plurality of fibrous layers stacked on one another in accordance with at least one embodiment;

FIG. 172 is a perspective view of an end effector insert and an end effector of a surgical instrument in accordance with at least one embodiment;

FIG. 173 is an elevational view of a tissue thickness compensator positioned in an end effector of a surgical instrument in accordance with at least one embodiment;

FIG. 174 is an elevational view of a tissue thickness compensator positioned in the end effector of the surgical instrument in accordance with at least one embodiment;

FIG. 175 is a perspective view of a sleeve positioned on an anvil for the end effector of the surgical instrument in accordance with at least one embodiment;

FIG. 176 is a plan view of a pronged portion of the sleeve of FIG. 175;

FIG. 177 is an elevational view of the pronged portion of the sleeve of FIG. 175;

FIG. 178 is an end view of the pronged portion of the sleeve of FIG. 175;

FIG. 179 is a perspective view of the pronged portion of the sleeve of FIG. 175;

FIG. 180 is a plan view of a tissue compensator of a sleeve in accordance with at least one embodiment;

FIG. 181 is a perspective view of the tissue compensator of FIG. 180;

FIG. 182 is an elevational view of the tissue compensator of FIG. 180;

FIG. 183 is a plan view of a tissue compensator of a sleeve in accordance with at least one embodiment;

FIG. 184 is a perspective view of the tissue compensator of FIG. 183;

FIG. 185 is an elevational view of the tissue compensator of FIG. 183;

FIG. 186 is a perspective view of a nose of the sleeve of FIG. 175;

FIG. 187 is another perspective view of the nose of FIG. 186;

FIG. 188 is a plan view of the nose of FIG. 186 depicting the inner geometry in phantom lines;

FIG. 189 is an elevational view of the nose of FIG. 186 depicting the inner geometry in phantom lines;

FIG. 190 is another perspective view of the sleeve of FIG. 175 positioned on the anvil;

FIG. 191 is a plan view of the sleeve of FIG. 175 positioned on the anvil;

FIG. 192 is an elevational view of the sleeve of FIG. 175 positioned on the anvil;

FIG. 193 is a plan view of the sleeve of FIG. 175 positioned on the anvil depicting a translating firing bar shown in phantom lines;

FIG. 194 is an elevational view of the sleeve of FIG. 175 positioned on the anvil depicting a translating firing bar shown in phantom lines;

FIG. 195 is a plan view of the sleeve of FIG. 175 positioned on the anvil depicting the release of the nose from the sleeve;

FIG. 196 is an elevational view of the sleeve of FIG. 175 positioned on the anvil depicting the release of the nose from the sleeve;

FIG. 197 is a plan view of the sleeve of FIG. 175 positioned on the anvil depicting the firing bar in phantom lines and the release of the nose from the sleeve;

FIG. 198 is an elevational view of the sleeve of FIG. 175 positioned on the anvil depicting the firing bar in phantom lines and the release of the nose from the sleeve;

FIG. 199 is a partial perspective view of the sleeve, the anvil, and the firing bar of FIG. 197;

FIG. 200 is another partial perspective view of the sleeve, the anvil, and the firing bar of FIG. 197;

FIG. 201 is an elevational cross-sectional view of the sleeve and the anvil of FIG. 175;

FIG. 202 is an elevational cross-sectional view of the anvil of FIG. 175 depicting the release of the tissue compensator from the sleeve;

FIG. 203 is a plan view of an end effector insert in accordance with at least one embodiment;

FIG. 204 is an elevational view of the end effector insert of FIG. 203;

FIG. 205 is a perspective view of the end effector insert of FIG. 205;

FIG. 206 is a partial perspective view of the end effector insert of FIG. 203 depicting the end effector insert engaging the anvil of the end effector of a surgical instrument;

FIG. 207 is a partial perspective view of the end effector insert of FIG. 203 depicting the end effector insert engaging the staple cartridge of the end effector of a surgical instrument;

FIG. 208 is an elevational view of the end effector insert of FIG. 203 depicting the end effector insert engaging the end effector of a surgical instrument;

FIG. 209 is an elevational view of the end effector insert of FIG. 203 positioned in the end effector of a surgical instrument;

FIG. 210 is a perspective view of a tissue thickness compensator positioned in the end effector of a surgical instrument in accordance with at least one embodiment illustrated with a portion of the tissue thickness compensator cut away;

FIG. 211 is a perspective view of the tissue thickness compensator of FIG. 210 secured to the anvil of the end effector by a static charge;

FIG. 212 is a perspective view of the tissue thickness compensator of FIG. 210 secured to the anvil of the end effector by suction elements;

FIG. 213 is a perspective view of the tissue thickness compensator of FIG. 210 secured to the anvil of the end effector by hook and loop fasteners;

FIG. 214 is a partial perspective view of the tissue thickness compensator of FIG. 210 secured to the anvil of the end effector by a band;

FIG. 215 is a partial perspective view of the tissue thickness compensator of FIG. 210 secured to the anvil of the end effector by a sock at the distal end of the tissue thickness compensator;

FIG. 216 is a perspective partial cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of a surgical instrument in accordance with at least one embodiment;

FIG. 217 is an elevational cross-sectional view of the tissue thickness compensator of FIG. 216;

FIG. 218 is another elevational cross-sectional view of the tissue thickness compensator of FIG. 216;

FIG. 219 is an elevational cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of a surgical instrument depicting a latch in a closed position in accordance with at least one embodiment;

FIG. 220 is an elevational cross-sectional view the tissue thickness compensator of FIG. 219 depicting the latch in the open position;

FIG. 221 is an elevational cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of a surgical instrument in accordance with at least one embodiment;

FIG. 222 is an elevational cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of a surgical instrument in accordance with at least one embodiment;

FIG. 223 is an elevational cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of a surgical instrument in accordance with at least one embodiment;

FIG. 224 is an elevational cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of the surgical instrument in accordance with at least one embodiment;

FIG. 225 is a perspective cross-sectional exploded view of a tissue thickness compensator secured to an anvil of an end effector of the surgical instrument in accordance with at least one embodiment;

FIG. 226 is a perspective view of the tissue thickness compensator of FIG. 225 depicting movement of the tissue thickness compensator towards the anvil;

FIG. 227 is an elevational cross-sectional view of the tissue thickness compensator of FIG. 225 engaged with the anvil;

FIG. 228 is a perspective cross-sectional view of a tissue thickness compensator secured to the anvil of the end effector of a surgical instrument in accordance with at least one embodiment;



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FIG. 229 is a perspective cross-sectional exploded view of the tissue thickness compensator and the anvil of FIG. 228;

FIG. 230 is an elevational view of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 231 is a perspective view of the tissue thickness compensator of FIG. 230;

FIG. 232 is another perspective of the tissue thickness compensator of FIG. 230;

FIG. 233 is a perspective view of the tissue thickness compensator of FIG. 230 depicting movement of the tissue thickness compensator towards the anvil of the end effector of a surgical instrument;

FIG. 234 is a plan cross-sectional view of the tissue thickness compensator of FIG. 230 positioned on the anvil;

FIG. 235 is a perspective view of the tissue thickness compensator of FIG. 230 positioned on the anvil;

FIG. 236 is a perspective view of the tissue thickness compensator of FIG. 230 positioned on the anvil illustrating a cutting element severing the tissue thickness compensator;

FIG. 237 is a cross-sectional elevational view of an end effector of a surgical stapling instrument comprising an anvil and a chargeable layer in accordance with at least one embodiment;

FIG. 238 is a bottom view of the anvil and the chargeable layer of FIG. 237;

FIG. 239 is an exploded view of the anvil and the chargeable layer of FIG. 237 and a tissue thickness compensator releasably attachable to the chargeable layer;

FIG. 240 is a perspective view of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 241 is a plan view of the tissue thickness compensator of FIG. 240;

FIG. 240A is a perspective view of a tissue thickness compensator in accordance with at least one alternative embodiment;

FIG. 241A is a plan view of the tissue thickness compensator of FIG. 240A;

FIG. 242 is a perspective view of a tissue thickness compensator in accordance with at least one alternative embodiment;

FIG. 243 is a plan view of the tissue thickness compensator of FIG. 242;

FIG. 244 is a perspective view of a tissue thickness compensator in accordance with at least one embodiment;

FIG. 245 is a perspective view of a tissue thickness compensator attached to an anvil in accordance with at least one embodiment;

FIG. 246 is a cross-sectional view of the anvil and the tissue thickness compensator of FIG. 245;

FIG. 247 is a cross-sectional view of the tissue thickness compensator of FIG. 245;

FIG. 248 is a perspective view of a tissue thickness compensator attached to an anvil in accordance with at least one alternative embodiment;

FIG. 249 is a cross-sectional view of the anvil and the tissue thickness compensator of FIG. 248;

FIG. 250 is a cross-sectional view of the tissue thickness compensator of FIG. 248 in an open configuration;

FIG. 251 is a perspective view of a tissue thickness compensator attached to an anvil in accordance with at least one alternative embodiment;

FIG. 252 is a cross-sectional view of the anvil and the tissue thickness compensator of FIG. 251;

FIG. 253 is a perspective view of a tissue thickness compensator attached to an anvil in accordance with at least one alternative embodiment;

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FIG. 254 is a cross-sectional view of the anvil and the tissue thickness compensator of FIG. 253;

FIG. 255 is a perspective view of a tissue thickness compensator attached to an anvil in accordance with at least one alternative embodiment;

FIG. 256 is a cross-sectional view of the anvil and the tissue thickness compensator of FIG. 255;

FIG. 257 is a perspective view of a tissue thickness compensator attached to an anvil in accordance with at least one alternative embodiment; and

FIG. 258 is a cross-sectional view of the anvil and the tissue thickness compensator of FIG. 257.

Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate certain embodiments of the invention, in one form, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

#### DETAILED DESCRIPTION

The Applicant of the present application also owns the U.S. Patent Applications identified below which are each herein incorporated by reference in their respective entirety:

U.S. patent application Ser. No. 12/894,311, entitled SURGICAL INSTRUMENTS WITH RECONFIGURABLE SHAFT SEGMENTS, now U.S. Pat. No. 8,763,877;

U.S. patent application Ser. No. 12/894,340, entitled SURGICAL STAPLE CARTRIDGES SUPPORTING NON-LINEARLY ARRANGED STAPLES AND SURGICAL STAPLING INSTRUMENTS WITH COMMON STAPLE-FORMING POCKETS, now U.S. Pat. No. 8,899,463;

U.S. patent application Ser. No. 12/894,327, entitled JAW CLOSURE ARRANGEMENTS FOR SURGICAL INSTRUMENTS, now U.S. Pat. No. 8,978,956;

U.S. patent application Ser. No. 12/894,351, entitled SURGICAL CUTTING AND FASTENING INSTRUMENTS WITH SEPARATE AND DISTINCT FASTENER DEPLOYMENT AND TISSUE CUTTING SYSTEMS, now U.S. Patent Application Publication No. 2012-0080502;

U.S. patent application Ser. No. 12/894,338, entitled IMPLANTABLE FASTENER CARTRIDGE HAVING A NON-UNIFORM ARRANGEMENT, now U.S. Pat. No. 8,864,007;

U.S. patent application Ser. No. 12/894,369, entitled IMPLANTABLE FASTENER CARTRIDGE COMPRISING A SUPPORT RETAINER, now U.S. Patent Application Publication No. 2012-0080344;

U.S. patent application Ser. No. 12/894,312, entitled IMPLANTABLE FASTENER CARTRIDGE COMPRISING MULTIPLE LAYERS, now U.S. Pat. No. 8,925,782;

U.S. patent application Ser. No. 12/894,377, entitled SELECTIVELY ORIENTABLE IMPLANTABLE FASTENER CARTRIDGE, now U.S. Pat. No. 8,393,514;

U.S. patent application Ser. No. 12/894,339, entitled SURGICAL STAPLING INSTRUMENT WITH COMPACT ARTICULATION CONTROL ARRANGEMENT, now U.S. Pat. No. 8,840,003;

U.S. patent application Ser. No. 12/894,360, entitled SURGICAL STAPLING INSTRUMENT WITH A VARIABLE STAPLE FORMING SYSTEM, now U.S. Patent Application Publication No. 2012-0080484;

U.S. patent application Ser. No. 12/894,322, entitled SURGICAL STAPLING INSTRUMENT WITH INTERCHANGEABLE STAPLE CARTRIDGE ARRANGEMENTS, now U.S. Pat. No. 8,740,034;

U.S. patent application Ser. No. 12/894,350, entitled SURGICAL STAPLE CARTRIDGES WITH DETACHABLE

SUPPORT STRUCTURES AND SURGICAL STAPLING INSTRUMENTS WITH SYSTEMS FOR PREVENTING ACTUATION MOTIONS WHEN A CARTRIDGE IS NOT PRESENT, now U.S. Patent Application Publication No. 2012-0080478;

U.S. patent application Ser. No. 12/894,383, entitled IMPLANTABLE FASTENER CARTRIDGE COMPRISING BIOABSORBABLE LAYERS, now U.S. Pat. No. 8,752,699;

U.S. patent application Ser. No. 12/894,389, entitled COMPRESSIBLE FASTENER CARTRIDGE, now U.S. Pat. No. 8,740,037;

U.S. patent application Ser. No. 12/894,345, entitled FASTENERS SUPPORTED BY A FASTENER CARTRIDGE SUPPORT, now U.S. Pat. No. 8,783,542;

U.S. patent application Ser. No. 12/894,306, entitled COLLAPSIBLE FASTENER CARTRIDGE now U.S. Pat. No. 9,044,227;

U.S. patent application Ser. No. 12/894,318, entitled FASTENER SYSTEM COMPRISING A PLURALITY OF CONNECTED RETENTION MATRIX ELEMENTS, now U.S. Pat. No. 8,814,024;

U.S. patent application Ser. No. 12/894,330, entitled FASTENER SYSTEM COMPRISING A RETENTION MATRIX AND AN ALIGNMENT MATRIX, now U.S. Pat. No. 8,757,465;

U.S. patent application Ser. No. 12/894,361, entitled FASTENER SYSTEM COMPRISING A RETENTION MATRIX, now U.S. Pat. No. 8,529,600;

U.S. patent application Ser. No. 12/894,367, entitled FASTENING INSTRUMENT FOR DEPLOYING A FASTENER SYSTEM COMPRISING A RETENTION MATRIX now U.S. Pat. No. 9,033,203;

U.S. patent application Ser. No. 12/894,388, entitled FASTENER SYSTEM COMPRISING A RETENTION MATRIX AND A COVER, now U.S. Pat. No. 8,474,677;

U.S. patent application Ser. No. 12/894,376, entitled FASTENER SYSTEM COMPRISING A PLURALITY OF FASTENER CARTRIDGES now U.S. Pat. No. 9,044,228;

U.S. patent application Ser. No. 13/097,865, entitled SURGICAL STAPLER ANVIL COMPRISING A PLURALITY OF FORMING POCKETS, now U.S. Patent Application Publication No. 2012-0080488;

U.S. patent application Ser. No. 13/097,936, entitled TISSUE THICKNESS COMPENSATOR FOR A SURGICAL STAPLER, now U.S. Pat. No. 8,657,176;

U.S. patent application Ser. No. 13/097,954, entitled STAPLE CARTRIDGE COMPRISING A VARIABLE THICKNESS COMPRESSIBLE PORTION, now U.S. Patent Application Publication No. 2012-0080340;

U.S. patent application Ser. No. 13/097,856, entitled STAPLE CARTRIDGE COMPRISING STAPLES POSITIONED WITHIN A COMPRESSIBLE PORTION THEREOF, now U.S. Patent Application Publication No. 2012-0080336;

U.S. patent application Ser. No. 13/097,928, entitled TISSUE THICKNESS COMPENSATOR COMPRISING DETACHABLE PORTIONS, now U.S. Pat. No. 8,746,535;

U.S. patent application Ser. No. 13/097,891, entitled TISSUE THICKNESS COMPENSATOR FOR A SURGICAL STAPLER COMPRISING AN ADJUSTABLE ANVIL, now U.S. Pat. No. 8,864,009;

U.S. patent application Ser. No. 13/097,948, entitled STAPLE CARTRIDGE COMPRISING AN ADJUSTABLE DISTAL PORTION, now U.S. Pat. No. 8,978,954;

U.S. patent application Ser. No. 13/097,907, entitled COMPRESSIBLE STAPLE CARTRIDGE ASSEMBLY, now U.S. Patent Application Publication No. 2012-0080338;

U.S. patent application Ser. No. 13/097,861, entitled TISSUE THICKNESS COMPENSATOR COMPRISING PORTIONS HAVING DIFFERENT PROPERTIES, now U.S. Patent Application Publication No. 2012-0080337;

U.S. patent application Ser. No. 13/097,869, entitled STAPLE CARTRIDGE LOADING ASSEMBLY, now U.S. Pat. No. 8,857,694;

U.S. patent application Ser. No. 13/097,917, entitled COMPRESSIBLE STAPLE CARTRIDGE COMPRISING ALIGNMENT MEMBERS, now U.S. Pat. No. 8,777,004;

U.S. patent application Ser. No. 13/097,873, entitled STAPLE CARTRIDGE COMPRISING A RELEASABLE PORTION, now U.S. Pat. No. 8,740,038;

U.S. patent application Ser. No. 13/097,938, entitled STAPLE CARTRIDGE COMPRISING COMPRESSIBLE DISTORTION RESISTANT COMPONENTS, now U.S. Pat. No. 9,016,542;

U.S. patent application Ser. No. 13/097,924, entitled STAPLE CARTRIDGE COMPRISING A TISSUE THICKNESS COMPENSATOR, now U.S. Patent Application Publication No. 2012-0083835;

U.S. patent application Ser. No. 13/242,029, entitled SURGICAL STAPLER WITH FLOATING ANVIL, now U.S. Pat. No. 8,893,949;

U.S. patent application Ser. No. 13/242,066, entitled CURVED END EFFECTOR FOR A STAPLING INSTRUMENT, now U.S. Patent Application Publication No. 2012-0080498;

U.S. patent application Ser. No. 13/242,086, entitled STAPLE CARTRIDGE INCLUDING COLLAPSIBLE DECK now U.S. Pat. No. 9,055,941;

U.S. patent application Ser. No. 13/241,912, entitled STAPLE CARTRIDGE INCLUDING COLLAPSIBLE DECK ARRANGEMENT, now U.S. Pat. No. 9,050,084;

U.S. patent application Ser. No. 13/241,922, entitled SURGICAL STAPLER WITH STATIONARY STAPLE DRIVERS, now U.S. Patent Application Publication No. 2013-0075449;

U.S. patent application Ser. No. 13/241,637, entitled SURGICAL INSTRUMENT WITH TRIGGER ASSEMBLY FOR GENERATING MULTIPLE ACTUATION MOTIONS, now U.S. Pat. No. 8,789,741; and

U.S. patent application Ser. No. 13/241,629, entitled SURGICAL INSTRUMENT WITH SELECTIVELY ARTICULATABLE END EFFECTOR, now U.S. Patent Application Publication No. 2012-0074200.

The Applicant of the present application also owns the U.S. Patent Applications identified below which were filed on Mar. 28, 2012 and which are each herein incorporated by reference in their respective entirety:

U.S. application Ser. No. 13/433,096, entitled TISSUE THICKNESS COMPENSATOR COMPRISING A PLURALITY OF CAPSULES, now U.S. Patent Application Publication No. 2012-0241496;

U.S. application Ser. No. 13/433,103, entitled TISSUE THICKNESS COMPENSATOR COMPRISING A PLURALITY OF LAYERS, now U.S. Patent Application Publication No. 2012-0241498;

U.S. application Ser. No. 13/433,098, entitled EXPANDABLE TISSUE THICKNESS COMPENSATOR, now U.S. Patent Application Publication No. 2012-0241491;

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U.S. application Ser. No. 13/433,102, entitled TISSUE THICKNESS COMPENSATOR COMPRISING A RESERVOIR, now U.S. Patent Application Publication No. 2012-0241497;

U.S. application Ser. No. 13/433,114, entitled RETAINER ASSEMBLY INCLUDING A TISSUE THICKNESS COMPENSATOR, now U.S. Patent Application Publication No. 2012-0241499;

U.S. application Ser. No. 13/433,136, entitled TISSUE THICKNESS COMPENSATOR COMPRISING AT LEAST ONE MEDICAMENT, now U.S. Patent Application Publication No. 2012-0241492;

U.S. application Ser. No. 13/433,141, entitled TISSUE THICKNESS COMPENSATOR COMPRISING CONTROLLED RELEASE AND EXPANSION, now U.S. Patent Application Publication No. 2012-0241493;

U.S. application Ser. No. 13/433,144, entitled TISSUE THICKNESS COMPENSATOR COMPRISING FIBERS TO PRODUCE A RESILIENT LOAD, now U.S. Patent Application Publication No. 2012-0241500;

U.S. application Ser. No. 13/433,148, entitled TISSUE THICKNESS COMPENSATOR COMPRISING STRUCTURE TO PRODUCE A RESILIENT LOAD, now U.S. Patent Application Publication No. 2012-0241501;

U.S. application Ser. No. 13/433,155, entitled TISSUE THICKNESS COMPENSATOR COMPRISING RESILIENT MEMBERS, now U.S. Patent Application Publication No. 2012-0241502;

U.S. application Ser. No. 13/433,163, entitled METHODS FOR FORMING TISSUE THICKNESS COMPENSATOR ARRANGEMENTS FOR SURGICAL STAPLERS, now U.S. Patent Application Publication No. 2012-0248169;

U.S. application Ser. No. 13/433,167, entitled TISSUE THICKNESS COMPENSATORS, now U.S. Patent Application Publication No. 2012-0241503;

U.S. application Ser. No. 13/433,175, entitled LAYERED TISSUE THICKNESS COMPENSATOR, now U.S. Patent Application Publication No. 2012-0253298;

U.S. application Ser. No. 13/433,179, entitled TISSUE THICKNESS COMPENSATORS FOR CIRCULAR SURGICAL STAPLERS, now U.S. Patent Application Publication No. 2012-0241505;

U.S. application Ser. No. 13/433,115, entitled TISSUE THICKNESS COMPENSATOR COMPRISING CAPSULES DEFINING A LOW PRESSURE ENVIRONMENT, now U.S. Patent Application Publication No. 2013-0256372;

U.S. application Ser. No. 13/433,118, entitled TISSUE THICKNESS COMPENSATOR COMPRISED OF A PLURALITY OF MATERIALS, now U.S. Patent Application Publication No. 2013-0256365;

U.S. application Ser. No. 13/433,135, entitled MOVABLE MEMBER FOR USE WITH A TISSUE THICKNESS COMPENSATOR, now U.S. Patent Application Publication No. 2013-0256382;

U.S. application Ser. No. 13/433,140, entitled TISSUE THICKNESS COMPENSATOR AND METHOD FOR MAKING THE SAME, now U.S. Patent Application Publication No. 2013-0256368;

U.S. application Ser. No. 13/433,147, entitled TISSUE THICKNESS COMPENSATOR COMPRISING CHANNELS, now U.S. Patent Application Publication No. 2013-0256369;

U.S. application Ser. No. 13/433,126, entitled TISSUE THICKNESS COMPENSATOR COMPRISING TISSUE INGROWTH FEATURES, now U.S. Patent Application Publication No. 2013-0256366; and

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U.S. application Ser. No. 13/433,132, entitled DEVICES AND METHODS FOR ATTACHING TISSUE THICKNESS COMPENSATING MATERIALS TO SURGICAL STAPLING INSTRUMENTS, now U.S. Patent Application Publication No. 2013-0256373.

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the various embodiments of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

Reference throughout the specification to “various embodiments,” “some embodiments,” “one embodiment,” or “an embodiment,” or the like, means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment,” or the like, in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation. Such modifications and variations are intended to be included within the scope of the present invention.

The terms “proximal” and “distal” are used herein with reference to a clinician manipulating the handle portion of the surgical instrument. The term “proximal” referring to the portion closest to the clinician and the term “distal” referring to the portion located away from the clinician. It will be further appreciated that, for convenience and clarity, spatial terms such as “vertical”, “horizontal”, “up”, and “down” may be used herein with respect to the drawings. However, surgical instruments are used in many orientations and positions, and these terms are not intended to be limiting and/or absolute.

Various exemplary devices and methods are provided for performing laparoscopic and minimally invasive surgical procedures. However, the person of ordinary skill in the art will readily appreciate that the various methods and devices disclosed herein can be used in numerous surgical procedures and applications including, for example, in connection with open surgical procedures. As the present Detailed Description proceeds, those of ordinary skill in the art will further appreciate that the various instruments disclosed herein can be inserted into a body in any way, such as through a natural orifice, through an incision or puncture hole formed in tissue, etc. The working portions or end effector portions of the instruments can be inserted directly into a patient's body or can be inserted through an access device that has a working channel through which the end effector and elongated shaft of a surgical instrument can be advanced.

Turning to the Drawings wherein like numerals denote like components throughout the several views, FIG. 1 depicts a

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surgical instrument **10** that is capable of practicing several unique benefits. The surgical stapling instrument **10** is designed to manipulate and/or actuate various forms and sizes of end effectors **12** that are operably attached thereto. In the embodiment depicted in FIGS. 1-1E, for example, the end effector **12** includes an elongated channel **14** that forms a lower jaw **13** of the end effector **12**. The elongated channel **14** is configured to support an "implantable" staple cartridge **30** and also movably support an anvil **20** that functions as an upper jaw **15** of the end effector **12**.

In various embodiments, the elongated channel **14** may be fabricated from, for example, 300 & 400 Series, 17-4 & 17-7 stainless steel, titanium, etc. and be formed with spaced side walls **16**. The anvil **20** may be fabricated from, for example, 300 & 400 Series, 17-4 & 17-7 stainless steel, titanium, etc. and have a staple forming undersurface, generally labeled as **22** that has a plurality of staple forming pockets **23** formed therein. See FIGS. 1B-1E. In addition, the anvil **20** has a bifurcated ramp assembly **24** that protrudes proximally therefrom. An anvil pin **26** protrudes from each lateral side of the ramp assembly **24** to be received within a corresponding slot or opening **18** in the side walls **16** of the elongated channel **14** to facilitate its movable or pivotable attachment thereto.

Various forms of implantable staple cartridges may be employed with the various embodiments of the surgical instruments disclosed herein. Specific staple cartridge configurations and constructions will be discussed in further detail below. However, in the embodiment depicted in FIG. 1A, an implantable staple cartridge **30** is shown. In at least one embodiment, the staple cartridge **30** has a body portion **31** that consists of a compressible hemostat material such as, for example, oxidized regenerated cellulose ("ORC") or a bioabsorbable foam in which lines of unformed metal staples **32** are supported. In at least some embodiments, in order to prevent the staple from being affected and the hemostat material from being activated during the introduction and positioning process, the entire cartridge may be coated or wrapped in a biodegradable film **38** such as a polydioxanone film sold under the trademark PDS® or with a Polyglycerol sebacate (PGS) film or other biodegradable films formed from PGA (Polyglycolic acid, marketed under the trade mark Vicryl), PCL (Polycaprolactone), PLA or PLLA (Polylactic acid), PHA (polyhydroxyalkanoate), PGCL (poliglecaprone 25, sold under the trademark Monocryl) or a composite of PGA, PCL, PLA, PDS that would be impermeable until ruptured. The body **31** of staple cartridge **30** is sized to be removably supported within the elongated channel **14** as shown such that each staple **32** therein is aligned with corresponding staple forming pockets **23** in the anvil when the anvil **20** is driven into forming contact with the staple cartridge **30**.

In use, once the end effector **12** has been positioned adjacent the target tissue, the end effector **12** is manipulated to capture or clamp the target tissue between an upper face **36** of the staple cartridge **30** and the staple forming surface **22** of the anvil **20**. The staples **32** are formed by moving the anvil **20** in a path that is substantially parallel to the elongated channel **14** to bring the staple forming surface **22** and, more particularly, the staple forming pockets **23** therein into substantially simultaneous contact with the upper face **36** of the staple cartridge **30**. As the anvil **20** continues to move into the staple cartridge **30**, the legs **34** of the staples **32** contact a corresponding staple forming pocket **23** in anvil **20** which serves to bend the staple legs **34** over to form the staples **32** into a "B shape". Further movement of the anvil **20** toward the elongated channel **14** will further compress and form the staples **32** to a desired final formed height "FF".

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The above-described staple forming process is generally depicted in FIGS. 1B-1E. For example, FIG. 1B illustrates the end effector **12** with target tissue "T" between the anvil **20** and the upper face **36** of the implantable staple cartridge **30**. FIG. 1C illustrates the initial clamping position of the anvil **20** wherein the anvil has **20** been closed onto the target tissue "T" to clamp the target tissue "T" between the anvil **20** and the upper face **36** of the staple cartridge **30**. FIG. 1D illustrates the initial staple formation wherein the anvil **20** has started to compress the staple cartridge **30** such that the legs **34** of the staples **32** are starting to be formed by the staple forming pockets **23** in the anvil **20**. FIG. 1E illustrates the staple **32** in its final formed condition through the target tissue "T" with the anvil **20** removed for clarity purposes. Once the staples **32** have been formed and fastened to the target tissue "T", the surgeon will move the anvil **20** to the open position to enable the cartridge body **31** and the staples **32** to remain affixed to the target tissue while the end effector **12** is being withdrawn from the patient. The end effector **12** forms all of the staples simultaneously as the two jaws **13**, **15** are clamped together. The remaining "crushed" body materials **31** act as both a hemostat (the ORC) and a staple line reinforcement (PGA, PDS or any of the other film compositions mentioned above **38**). Also, since the staples **32** never have to leave the cartridge body **31** during forming, the likelihood of the staples **32** being malformed during forming is minimized. As used herein the term "implantable" means that, in addition to the staples, the cartridge body materials that support the staples will also remain in the patient and may eventually be absorbed by the patient's body. Such implantable staple cartridges are distinguishable from prior cartridge arrangements that remain positioned within the end effector in their entirety after they have been fired.

In various implementations, the end effector **12** is configured to be coupled to an elongated shaft assembly **40** that protrudes from a handle assembly **100**. The end effector **12** (when closed) and the elongated shaft assembly **40** may have similar cross-sectional shapes and be sized to operably pass through a trocar tube or working channel in another form of access instrument. As used herein, the term "operably pass" means that the end effector and at least a portion of the elongated shaft assembly may be inserted through or passed through the channel or tube opening and can be manipulated therein as needed to complete the surgical stapling procedure. In some embodiments, when in a closed position, the jaws **13** and **15** of the end effector **12** may provide the end effector with a roughly circular cross-sectional shape that facilitates its passage through a circular passage/opening. However, the end effectors of various embodiments of the present invention, as well as the elongated shaft assembly embodiments, could conceivably be provided with other cross-sectional shapes that could otherwise pass through access passages and openings that have non-circular cross-sectional shapes. Thus, an overall size of a cross-section of a closed end effector will be related to the size of the passage or opening through which it is intended to pass. Thus, one end effector for example, may be referred to as a "5 mm" end effector which means it can operably pass through an opening that is at least approximately 5 mm in diameter.

In various embodiments, the elongated shaft assembly **40** may have an outer diameter that is substantially the same as the outer diameter of the end effector **12** when in a closed position. For example, a 5 mm end effector may be coupled to an elongated shaft assembly **40** that has 5 mm cross-sectional diameter. However, as the present Detailed Description proceeds, it will become apparent that various embodiments of the present may be effectively used in connection with differ-

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ent sizes of end effectors. For example, a 10 mm end effector may be attached to an elongated shaft that has a 5 mm cross-sectional diameter. Conversely, for those applications wherein a 10 mm or larger access opening or passage is provided, the elongated shaft assembly 40 may have a 10 mm (or larger) cross-sectional diameter, but may also be able to actuate a 5 mm or 10 mm end effector. Accordingly, the outer shaft 40 may have an outer diameter that is the same as or is different from the outer diameter of a closed end effector 12 attached thereto.

As depicted, the elongated shaft assembly 40 extends distally from the handle assembly 100 in a generally straight line to define a longitudinal axis A-A. In various embodiments, for example, the elongated shaft assembly 40 may be approximately 9-16 inches (229-406 mm) long. However, the elongated shaft assembly 40 may be provided in other lengths and, in other embodiments, may have joints therein or be otherwise configured to facilitate articulation of the end effector 12 relative to other portions of the shaft or handle assembly as will be discussed in further detail below. In various embodiments, the elongated shaft assembly 40 includes a spine member 50 that extends from the handle assembly 100 to the end effector 12. The proximal end of the elongated channel 14 of the end effector 12 has a pair of retention trunnions 17 protruding therefrom that are sized to be received within corresponding trunnion openings or cradles 52 that are provided in a distal end of the spine member 50 to enable the end effector 12 to be removably coupled the elongated shaft assembly 40. The spine member 50 may be fabricated from, for example, 6061 or 7075 aluminum, stainless steel, titanium, etc.

In various embodiments, the handle assembly 100 comprises a pistol grip-type housing that may be fabricated in two or more pieces for assembly purposes. For example, the handle assembly 100 as shown comprises a right hand case member 102 and a left hand case member (not illustrated) that are molded or otherwise fabricated from a polymer or plastic material and are designed to mate together. Such case members may be attached together by snap features, pegs and sockets molded or otherwise formed therein and/or by adhesive, screws, etc. The spine member 50 has a proximal end 54 that has a flange 56 formed thereon. The flange 56 is configured to be rotatably supported within a groove 106 formed by mating ribs 108 that protrude inwardly from each of the case members 102, 104. Such arrangement facilitates the attachment of the spine member 50 to the handle assembly 100 while enabling the spine member 50 to be rotated relative to the handle assembly 100 about the longitudinal axis A-A in a 360° path.

As can be further seen in FIG. 1, the spine member 50 passes through and is supported by a mounting bushing 60 that is rotatably affixed to the handle assembly 100. The mounting bushing 60 has a proximal flange 62 and a distal flange 64 that define a rotational groove 65 that is configured to rotatably receive a nose portion 101 of the handle assembly 100 therebetween. Such arrangement enables the mounting bushing 60 to rotate about longitudinal axis A-A relative to the handle assembly 100. The spine member 50 is non-rotatably pinned to the mounting bushing 60 by a spine pin 66. In addition, a rotation knob 70 is attached to the mounting bushing 60. In one embodiment, for example, the rotation knob 70 has a hollow mounting flange portion 72 that is sized to receive a portion of the mounting bushing 60 therein. In various embodiments, the rotation knob 70 may be fabricated from, for example, glass or carbon filled Nylon, polycarbonate, Ultem®, etc. and is affixed to the mounting bushing 60 by the spine pin 66 as well. In addition, an inwardly protruding retention flange 74 is formed on the mounting flange portion

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72 and is configured to extend into a radial groove 68 formed in the mounting bushing 60. Thus, the surgeon may rotate the spine member 50 (and the end effector 12 attached thereto) about longitudinal axis A-A in a 360° path by grasping the rotation knob 70 and rotating it relative to the handle assembly 100.

In various embodiments, the anvil 20 is retained in an open position by an anvil spring 21 and/or another biasing arrangement. The anvil 20 is selectively movable from the open position to various closed or clamping and firing positions by a firing system, generally designated as 109. The firing system 109 includes a "firing member" 110 which, in various embodiments, comprises a hollow firing tube 110. The hollow firing tube 110 is axially movable on the spine member 50 and thus forms the outer portion of the elongated shaft assembly 40. The firing tube 110 may be fabricated from a polymer or other suitable material and have a proximal end that is attached to a firing yoke 114 of the firing system 109. In various embodiments for example, the firing yoke 114 may be over-molded to the proximal end of the firing tube 110. However, other fastener arrangements may be employed.

As can be seen in FIG. 1, the firing yoke 114 may be rotatably supported within a support collar 120 that is configured to move axially within the handle assembly 100. In various embodiments, the support collar 120 has a pair of laterally extending fins that are sized to be slidably received within fin slots formed in the right and left hand case members. Thus, the support collar 120 may slide axially within the handle housing 100 while enabling the firing yoke 114 and firing tube 110 to rotate relative thereto about the longitudinal axis A-A. In various embodiments, a longitudinal slot is provided through the firing tube 110 to enable the spine pin 66 to extend therethrough into the spine member 50 while facilitating the axial travel of the firing tube 110 on the spine member 50.

The firing system 109 further comprises a firing trigger 130 which serves to control the axial travel of the firing tube 110 on the spine member 50. See FIG. 1. Such axial movement in the distal direction of the firing tube 110 into firing interaction with the anvil 20 is referred to herein as "firing motion". As can be seen in FIG. 1, the firing trigger 130 is movably or pivotally coupled to the handle assembly 100 by a pivot pin 132. A torsion spring 135 is employed to bias the firing trigger 130 away from the pistol grip portion 107 of the handle assembly 100 to an un-actuated "open" or starting position. As can be seen in FIG. 1, the firing trigger 130 has an upper portion 134 that is movably attached to (pinned) firing links 136 that are movably attached to (pinned) the support collar 120. Thus, movement of the firing trigger 130 from the starting position (FIG. 1) toward an ending position adjacent the pistol grip portion 107 of the handle assembly 100 will cause the firing yoke 114 and the firing tube 110 to move in the distal direction "DD". Movement of the firing trigger 130 away from the pistol grip portion 107 of the handle assembly 100 (under the bias of the torsion spring 135) will cause the firing yoke 114 and firing tube 110 to move in the proximal direction "PD" on the spine member 50.

Various embodiments of the present invention may be employed with different sizes and configurations of implantable staple cartridges. For example, the surgical instrument 10, when used in connection with a first firing adapter 140, may be used with a 5 mm end effector 12 that is approximately 20 mm long (or in other lengths) which supports an implantable staple cartridge 30. Such end effector size may be particularly well-suited, for example, to complete relatively fine dissection and vascular transactions. However, as will be discussed in further detail below, the surgical instrument 10

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may also be employed, for example, in connection with other sizes of end effectors and staple cartridges by replacing the first firing adapter 140 with a second firing adapter. In still other embodiments, the elongated shaft assembly 40 may be configured to be attached to only one form or size of end effector.

One method of removably coupling the end effector 12 to the spine member 50 will now be explained. The coupling process is commenced by inserting the retention trunnions 17 on the elongated channel 14 into the trunnion cradles 52 in the spine member 50. Thereafter, the surgeon advances the firing trigger 130 toward the pistol grip 107 of the housing assembly 100 to distally advance the firing tube 110 and the first firing adapter 140 over a proximal end portion 47 of the elongated channel 14 to thereby retain the trunnions 17 in their respective cradles 52. Such position of the first firing adapter 140 over the trunnions 17 is referred to herein as the "coupled position". Various embodiments of the present invention may also have an end effector locking assembly for locking the firing trigger 130 in position after an end effector 12 has been attached to the spine member 50.

More specifically, one embodiment of the end effector locking assembly 160 includes a retention pin 162 that is movably supported in the upper portion 134 of the firing trigger 130. As discussed above, the firing tube 110 must initially be advanced distally to the coupled position wherein the first firing adapter 140 retains the retention trunnions 17 of the end effector 12 in the trunnion cradles 52 in the spine member 50. The surgeon advances the firing adapter 140 distally to the coupled position by pulling the firing trigger 130 from the starting position toward the pistol grip 107. As the firing trigger 130 is initially actuated, the retention pin 162 is moved distally until the firing tube 110 has advanced the first firing adapter 140 to the coupled position at which point the retention pin 162 is biased into a locking cavity 164 formed in the case member. In various embodiments, when the retention pin 162 enters into the locking cavity 164, the pin 162 may make an audible "click" or other sound, as well as provide a tactile indication to the surgeon that the end effector 12 has been "locked" onto the spine member 50. In addition, the surgeon cannot inadvertently continue to actuate the firing trigger 130 to start to form staples 32 in the end effector 12 without intentionally biasing the retention pin 162 out of the locking cavity 164. Similarly, if the surgeon releases the firing trigger 130 when in the coupled position, it is retained in that position by the retention pin 162 to prevent the firing trigger 130 from returning to the starting position and thereby releasing the end effector 12 from the spine member 50.

Various embodiments of the present invention may further include a firing system lock button 137 that is pivotally attached to the handle assembly 100. In one form, the firing system lock button 137 has a latch 138 formed on a distal end thereof that is oriented to engage the firing yoke 114 when the firing release button is in a first latching position. As can be seen in FIG. 1, a latch spring 139 serves to bias the firing system lock button 137 to the first latching position. In various circumstances, the latch 138 serves to engage the firing yoke 114 at a point where the position of the firing yoke 114 on the spine member 50 corresponds to a point wherein the first firing adapter 140 is about to distally advance up the clamping ramp 28 on the anvil 20. It will be understood that, as the first firing adapter 140 advances axially up the clamping ramp 28, the anvil 20 will move in a path such that its staple forming surface portion 22 is substantially parallel to the upper face 36 of the staple cartridge 30.

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After the end effector 12 has been coupled to the spine member 50, the staple forming process is commenced by first depressing the firing system lock button 137 to enable the firing yoke 114 to be further moved distally on the spine member 50 and ultimately compress the anvil 20 into the staple cartridge 30. After depressing the firing system lock button 137, the surgeon continues to actuate the firing trigger 130 towards the pistol grip 107 thereby driving the first staple collar 140 up the corresponding staple forming ramp 29 to force the anvil 20 into forming contact with the staples 32 in the staple cartridge 30. The firing system lock button 137 prevents the inadvertent forming of the staples 32 until the surgeon is ready to start that process. In this embodiment, the surgeon must depress the firing system lock button 137 before the firing trigger 130 may be further actuated to begin the staple forming process.

The surgical instrument 10 may be solely used as a tissue stapling device if so desired. However, various embodiments of the present invention may also include a tissue cutting system, generally designated as 170. In at least one form, the tissue cutting system 170 comprises a knife member 172 that may be selectively advanced from an un-actuated position adjacent the proximal end of the end effector 12 to an actuated position by actuating a knife advancement trigger 200. The knife member 172 is movably supported within the spine member 50 and is attached or otherwise protrudes from a knife rod 180. The knife member 172 may be fabricated from, for example, 420 or 440 stainless steel with a hardness of greater than 38HRC (Rockwell Hardness C-scale) and have a tissue cutting edge 176 formed on the distal end 174 thereof and be configured to slidably extend through a slot in the anvil 20 and a centrally disposed slot 33 in the staple cartridge 30 to cut through tissue that is clamped in the end effector 12. In various embodiments, the knife rod 180 extends through the spine member 50 and has a proximal end portion which drivingly interfaces with a knife transmission that is operably attached to the knife advance trigger 200. In various embodiments, the knife advance trigger 200 is attached to pivot pin 132 such that it may be pivoted or otherwise actuated without actuating the firing trigger 130. In various embodiments, a first knife gear 192 is also attached to the pivot pin 132 such that actuation of the knife advance trigger 200 also pivots the first knife gear 192. A firing return spring 202 is attached between the first knife gear 192 and the handle housing 100 to bias the knife advancement trigger 200 to a starting or un-actuated position.

Various embodiments of the knife transmission also include a second knife gear 194 that is rotatably supported on a second gear spindle and in meshing engagement with the first knife gear 192. The second knife gear 194 is in meshing engagement with a third knife gear 196 that is supported on a third gear spindle. Also supported on the third gear spindle 195 is a fourth knife gear 198. The fourth knife gear 198 is adapted to drivingly engage a series of annular gear teeth or rings on a proximal end of the knife rod 180. Thus, such arrangement enables the fourth knife gear 198 to axially drive the knife rod 180 in the distal direction "DD" or proximal direction "PD" while enabling the firing rod 180 to rotate about longitudinal axis A-A with respect to the fourth knife gear 198. Accordingly, the surgeon may axially advance the firing rod 180 and ultimately the knife member 172 distally by pulling the knife advancement trigger 200 towards the pistol grip 107 of the handle assembly 100.

Various embodiments of the present invention further include a knife lockout system 210 that prevents the advancement of the knife member 172 unless the firing trigger 130 has been pulled to the fully fired position. Such feature will there-

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fore prevent the activation of the knife advancement system 170 unless the staples have first been fired or formed into the tissue. As can be seen in FIG. 1, various implementations of the knife lockout system 210 comprise a knife lockout bar 211 that is pivotally supported within the pistol grip portion 107 of the handle assembly 100. The knife lockout bar 211 has an activation end 212 that is adapted to be engaged by the firing trigger 130 when the firing trigger 130 is in the fully fired position. In addition, the knife lockout bar 211 has a retaining hook 214 on its other end that is adapted to hookingly engage a latch rod 216 on the first cut gear 192. A knife lock spring 218 is employed to bias the knife lockout bar 211 to a "locked" position wherein the retaining hook 214 is retained in engagement with the latch rod 216 to thereby prevent actuation of the knife advancement trigger 200 unless the firing trigger 130 is in the fully fired position.

After the staples have been "fired" (formed) into the target tissue, the surgeon may depress the firing trigger release button 167 to enable the firing trigger 130 to return to the starting position under the bias of the torsion spring 135 which enables the anvil 20 to be biased to an open position under the bias of spring 21. When in the open position, the surgeon may withdraw the end effector 12 leaving the implantable staple cartridge 30 and staples 32 behind. In applications wherein the end effector was inserted through a passage, working channel, etc. the surgeon will return the anvil 20 to the closed position by activating the firing trigger 130 to enable the end effector 12 to be withdrawn out through the passage or working channel. If, however, the surgeon desires to cut the target tissue after firing the staples, the surgeon activates the knife advancement trigger 200 in the above-described manner to drive the knife bar 172 through the target tissue to the end of the end effector. Thereafter, the surgeon may release the knife advancement trigger 200 to enable the firing return spring 202 to cause the firing transmission to return the knife bar 172 to the starting (un-actuated) position. Once the knife bar 172 has been returned to the starting position, the surgeon may open the end effector jaws 13, 15 to release the implantable cartridge 30 within the patient and then withdraw the end effector 12 from the patient. Thus, such surgical instruments facilitate the use of small implantable staple cartridges that may be inserted through relatively smaller working channels and passages, while providing the surgeon with the option to fire the staples without cutting tissue or if desired to also cut tissue after the staples have been fired.

Various unique and novel embodiments of the present invention employ a compressible staple cartridge that supports staples in a substantially stationary position for forming contact by the anvil. In various embodiments, the anvil is driven into the unformed staples wherein, in at least one such embodiment, the degree of staple formation attained is dependent upon how far the anvil is driven into the staples. Such an arrangement provides the surgeon with the ability to adjust the amount of forming or firing pressure applied to the staples and thereby alter the final formed height of the staples. In other various embodiments of the present invention, surgical stapling arrangements can employ staple driving elements which can lift the staples toward the anvil. Such embodiments are described in greater detail further below.

In various embodiments, with regard to the embodiments described in detail above, the amount of firing motion that is applied to the movable anvil is dependent upon the degree of actuation of the firing trigger. For example, if the surgeon desires to attain only partially formed staples, then the firing trigger is only partially depressed inward towards the pistol grip 107. To attain more staple formation, the surgeon simply

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compresses the firing trigger further which results in the anvil being further driven into forming contact with the staples. As used herein, the term "forming contact" means that the staple forming surface or staple forming pockets have contacted the ends of the staple legs and have started to form or bend the legs over into a formed position. The degree of staple formation refers to how far the staple legs have been folded over and ultimately relates to the forming height of the staple as referenced above. Those of ordinary skill in the art will further understand that, because the anvil 20 moves in a substantially parallel relationship with respect to the staple cartridge as the firing motions are applied thereto, the staples are formed substantially simultaneously with substantially the same formed heights.

FIGS. 2 and 3 illustrate an alternative end effector 12' that is similar to the end effector 12' described above, except with the following differences that are configured to accommodate a knife bar 172'. The knife bar 172' is coupled to or protrudes from a knife rod 180 and is otherwise operated in the above described manner with respect to the knife bar 172. However, in this embodiment, the knife bar 172' is long enough to traverse the entire length of the end effector 12' and therefore, a separate distal knife member is not employed in the end effector 12'. The knife bar 172' has an upper transverse member 173' and a lower transverse member 175' formed thereon. The upper transverse member 173' is oriented to slidably transverse a corresponding elongated slot 250 in anvil 20" and the lower transverse member 175' is oriented to transverse an elongated slot 252 in the elongated channel 14" of the end effector 12". A disengagement slot (not shown) is also provided in the anvil 20" such that when the knife bar 172' has been driven to an ending position within end effector 12", the upper transverse member 173' drops through the corresponding slot to enable the anvil 20" to move to the open position to disengage the stapled and cut tissue. The anvil 20" may be otherwise identical to anvil 20 described above and the elongated channel 14" may be otherwise identical to elongated channel 14 described above.

In these embodiments, the anvil 20" is biased to a fully open position (FIG. 2) by a spring or other opening arrangement (not shown). The anvil 20" is moved between the open and fully clamped positions by the axial travel of the firing adapter 150 in the manner described above. Once the firing adapter 150 has been advanced to the fully clamped position (FIG. 3), the surgeon may then advance the knife bar 172" distally in the manner described above. If the surgeon desires to use the end effector as a grasping device to manipulate tissue, the firing adapter may be moved proximally to allow the anvil 20" to move away from the elongated channel 14" as represented in FIG. 4 in broken lines. In this embodiment, as the knife bar 172" moves distally, the upper transverse member 173' and the lower transverse member 175' draw the anvil 20" and elongated channel 14" together to achieve the desired staple formation as the knife bar 172" is advanced distally through the end effector 12". See FIG. 5. Thus, in this embodiment, staple formation occurs simultaneously with tissue cutting, but the staples themselves may be sequentially formed as the knife bar 172" is driven distally.

The unique and novel features of the various surgical staple cartridges and the surgical instruments of the present invention enable the staples in those cartridges to be arranged in one or more linear or non-linear lines. A plurality of such staple lines may be provided on each side of an elongated slot that is centrally disposed within the staple cartridge for receiving the tissue cutting member therethrough. In one arrangement, for example, the staples in one line may be substantially parallel with the staples in adjacent line(s) of

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staples, but offset therefrom. In still other embodiments, one or more lines of staples may be non-linear in nature. That is, the base of at least one staple in a line of staples may extend along an axis that is substantially transverse to the bases of other staples in the same staple line. For example, the lines of staples on each side of the elongated slot may have a zigzag appearance.

In various embodiments, a staple cartridge can comprise a cartridge body and a plurality of staples stored within the cartridge body. In use, the staple cartridge can be introduced into a surgical site and positioned on a side of the tissue being treated. In addition, a staple-forming anvil can be positioned on the opposite side of the tissue. In various embodiments, the anvil can be carried by a first jaw and the staple cartridge can be carried by a second jaw, wherein the first jaw and/or the second jaw can be moved toward the other. Once the staple cartridge and the anvil have been positioned relative to the tissue, the staples can be ejected from the staple cartridge body such that the staples can pierce the tissue and contact the staple-forming anvil. Once the staples have been deployed from the staple cartridge body, the staple cartridge body can then be removed from the surgical site. In various embodiments disclosed herein, a staple cartridge, or at least a portion of a staple cartridge, can be implanted with the staples. In at least one such embodiment, as described in greater detail further below, a staple cartridge can comprise a cartridge body which can be compressed, crushed, and/or collapsed by the anvil when the anvil is moved from an open position into a closed position. When the cartridge body is compressed, crushed, and/or collapsed, the staples positioned within the cartridge body can be deformed by the anvil. Alternatively, the jaw supporting the staple cartridge can be moved toward the anvil into a closed position. In either event, in various embodiments, the staples can be deformed while they are at least partially positioned within the cartridge body. In certain embodiments, the staples may not be ejected from the staple cartridge while, in some embodiments, the staples can be ejected from the staple cartridge along with a portion of the cartridge body.

Referring now to FIGS. 6A-6D, a compressible staple cartridge, such as staple cartridge 1000, for example, can comprise a compressible, implantable cartridge body 1010 and, in addition, a plurality of staples 1020 positioned in the compressible cartridge body 1010, although only one staple 1020 is depicted in FIGS. 6A-6D. FIG. 6A illustrates the staple cartridge 1000 supported by a staple cartridge support, or staple cartridge channel, 1030, wherein the staple cartridge 1000 is illustrated in an uncompressed condition. In such an uncompressed condition, the anvil 1040 may or may not be in contact with the tissue T. In use, the anvil 1040 can be moved from an open position into contact with the tissue T as illustrated in FIG. 6B and position the tissue T against the cartridge body 1010. Even though the anvil 1040 can position the tissue T against a tissue-contacting surface 1019 of staple cartridge body 1010, referring again to FIG. 6B, the staple cartridge body 1010 may be subjected to little, if any, compressive force or pressure at such point and the staples 1020 may remain in an unformed, or unfired, condition. As illustrated in FIGS. 6A and 6B, the staple cartridge body 1010 can comprise one or more layers and the staple legs 1021 of staples 1020 can extend upwardly through these layers. In various embodiments, the cartridge body 1010 can comprise a first layer 1011, a second layer 1012, a third layer 1013, wherein the second layer 1012 can be positioned intermediate the first layer 1011 and the third layer 1013, and a fourth layer 1014, wherein the third layer 1013 can be positioned intermediate the second layer 1012 and the fourth layer 1014. In at

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least one embodiment, the bases 1022 of the staples 1020 can be positioned within cavities 1015 in the fourth layer 1014 and the staple legs 1021 can extend upwardly from the bases 1022 and through the fourth layer 1014, the third layer 1013, and the second layer 1012, for example. In various embodiments, each deformable leg 1021 can comprise a tip, such as sharp tip 1023, for example, which can be positioned in the second layer 1012, for example, when the staple cartridge 1000 is in an uncompressed condition. In at least one such embodiment, the tips 1023 may not extend into and/or through the first layer 1011, wherein, in at least one embodiment, the tips 1023 may not protrude through the tissue-contacting surface 1019 when the staple cartridge 1000 is in an uncompressed condition. In certain other embodiments, the sharp tips 1023 may be positioned in the third layer 1013, and/or any other suitable layer, when the staple cartridge is in an uncompressed condition. In various alternative embodiments, a cartridge body of a staple cartridge may have any suitable number of layers such as less than four layers or more than four layers, for example.

In various embodiments, as described in greater detail below, the first layer 1011 can be comprised of a buttress material and/or plastic material, such as polydioxanone (PDS) and/or polyglycolic acid (PGA), for example, and the second layer 1012 can be comprised of a bioabsorbable foam material and/or a compressible haemostatic material, such as oxidized regenerated cellulose (ORC), for example. In various embodiments, one or more of the first layer 1011, the second layer 1012, the third layer 1013, and the fourth layer 1014 may hold the staples 1020 within the staple cartridge body 1010 and, in addition, maintain the staples 1020 in alignment with one another. In various embodiments, the third layer 1013 can be comprised of a buttress material, or a fairly incompressible or inelastic material, which can be configured to hold the staple legs 1021 of the staples 1020 in position relative to one another. Furthermore, the second layer 1012 and the fourth layer 1014, which are positioned on opposite sides of the third layer 1013, can stabilize, or reduce the movement of, the staples 1020 even though the second layer 1012 and the fourth layer 1014 can be comprised of a compressible foam or elastic material. In certain embodiments, the staple tips 1023 of the staple legs 1021 can be at least partially embedded in the first layer 1011. In at least one such embodiment, the first layer 1011 and the third layer 1013 can be configured to co-operatively and firmly hold the staple legs 1021 in position. In at least one embodiment, the first layer 1011 and the third layer 1013 can each be comprised of a sheet of bioabsorbable plastic, such as polyglycolic acid (PGA) which is marketed under the trade name Vicryl, polylactic acid (PLA or PLLA), polydioxanone (PDS), polyhydroxyalkanoate (PHA), poliglecaprone 25 (PGCL) which is marketed under the trade name Monocryl, polycaprolactone (PCL), and/or a composite of PGA, PLA, PDS, PHA, PGCL and/or PCL, for example, and the second layer 1012 and the fourth layer 1014 can each be comprised of at least one haemostatic material or agent.

Although the first layer 1011 can be compressible, the second layer 1012 can be substantially more compressible than the first layer 1011. For example, the second layer 1012 can be about twice as compressible, about three times as compressible, about four times as compressible, about five times as compressible, and/or about ten times as compressible, for example, as the first layer 1011. Stated another way, the second layer 1012 may compress about two times, about three times, about four times, about five times, and/or about ten times as much as first layer 1011, for a given force. In certain embodiments, the second layer 1012 can be between



about twice as compressible and about ten times as compressible, for example, as the first layer **1011**. In at least one embodiment, the second layer **1012** can comprise a plurality of air voids defined therein, wherein the amount and/or size of the air voids in the second layer **1012** can be controlled in order to provide a desired compressibility of the second layer **1012**. Similar to the above, although the third layer **1013** can be compressible, the fourth layer **1014** can be substantially more compressible than the third layer **1013**. For example, the fourth layer **1014** can be about twice as compressible, about three times as compressible, about four times as compressible, about five times as compressible, and/or about ten times as compressible, for example, as the third layer **1013**. Stated another way, the fourth layer **1014** may compress about two times, about three times, about four times, about five times, and/or about ten times as much as third layer **1013**, for a given force. In certain embodiments, the fourth layer **1014** can be between about twice as compressible and about ten times as compressible, for example, as the third layer **1013**. In at least one embodiment, the fourth layer **1014** can comprise a plurality of air voids defined therein, wherein the amount and/or size of the air voids in the fourth layer **1014** can be controlled in order to provide a desired compressibility of the fourth layer **1014**. In various circumstances, the compressibility of a cartridge body, or cartridge body layer, can be expressed in terms of a compression rate, i.e., a distance in which a layer is compressed for a given amount of force. For example, a layer having a high compression rate will compress a larger distance for a given amount of compressive force applied to the layer as compared to a layer having a lower compression rate. This being said, the second layer **1012** can have a higher compression rate than the first layer **1011** and, similarly, the fourth layer **1014** can have a higher compression rate than the third layer **1013**. In various embodiments, the second layer **1012** and the fourth layer **1014** can be comprised of the same material and can comprise the same compression rate. In various embodiments, the second layer **1012** and the fourth layer **1014** can be comprised of materials having different compression rates. Similarly, the first layer **1011** and the third layer **1013** can be comprised of the same material and can comprise the same compression rate. In certain embodiments, the first layer **1011** and the third layer **1013** can be comprised of materials having different compression rates.

As the anvil **1040** is moved toward its closed position, the anvil **1040** can contact tissue **T** and apply a compressive force to the tissue **T** and the staple cartridge **1000**, as illustrated in FIG. **6C**. In such circumstances, the anvil **1040** can push the top surface, or tissue-contacting surface **1019**, of the cartridge body **1010** downwardly toward the staple cartridge support **1030**. In various embodiments, the staple cartridge support **1030** can comprise a cartridge support surface **1031** which can be configured to support the staple cartridge **1000** as the staple cartridge **1000** is compressed between the cartridge support surface **1031** and the tissue-contacting surface **1041** of anvil **1040**. Owing to the pressure applied by the anvil **1040**, the cartridge body **1010** can be compressed and the anvil **1040** can come into contact with the staples **1020**. More particularly, in various embodiments, the compression of the cartridge body **1010** and the downward movement of the tissue-contacting surface **1019** can cause the tips **1023** of the staple legs **1021** to pierce the first layer **1011** of cartridge body **1010**, pierce the tissue **T**, and enter into forming pockets **1042** in the anvil **1040**. As the cartridge body **1010** is further compressed by the anvil **1040**, the tips **1023** can contact the walls defining the forming pockets **1042** and, as a result, the legs **1021** can be deformed or curled inwardly, for example, as illustrated in FIG. **6C**. As the staple legs **1021** are being

deformed, as also illustrated in FIG. **6C**, the bases **1022** of the staples **1020** can be in contact with or supported by the staple cartridge support **1030**. In various embodiments, as described in greater detail below, the staple cartridge support **1030** can comprise a plurality of support features, such as staple support grooves, slots, or troughs **1032**, for example, which can be configured to support the staples **1020**, or at least the bases **1022** of the staples **1020**, as the staples **1020** are being deformed. As also illustrated in FIG. **6C**, the cavities **1015** in the fourth layer **1014** can collapse as a result of the compressive force applied to the staple cartridge body **1010**. In addition to the cavities **1015**, the staple cartridge body **1010** can further comprise one or more voids, such as voids **1016**, for example, which may or may not comprise a portion of a staple positioned therein, that can be configured to allow the cartridge body **1010** to collapse. In various embodiments, the cavities **1015** and/or the voids **1016** can be configured to collapse such that the walls defining the cavities and/or walls deflect downwardly and contact the cartridge support surface **1031** and/or contact a layer of the cartridge body **1010** positioned underneath the cavities and/or voids.

Upon comparing FIG. **6B** and FIG. **6C**, it is evident that the second layer **1012** and the fourth layer **1014** have been substantially compressed by the compressive pressure applied by the anvil **1040**. It may also be noted that the first layer **1011** and the third layer **1013** have been compressed as well. As the anvil **1040** is moved into its closed position, the anvil **1040** may continue to further compress the cartridge body **1010** by pushing the tissue-contacting surface **1019** downwardly toward the staple cartridge support **1030**. As the cartridge body **1010** is further compressed, the anvil **1040** can deform the staples **1020** into their completely-formed shape as illustrated in FIG. **6D**. Referring to FIG. **6D**, the legs **1021** of each staple **1020** can be deformed downwardly toward the base **1022** of each staple **1020** in order to capture at least a portion of the tissue **T**, the first layer **1011**, the second layer **1012**, the third layer **1013**, and the fourth layer **1014** between the deformable legs **1021** and the base **1022**. Upon comparing FIGS. **6C** and **6D**, it is further evident that the second layer **1012** and the fourth layer **1014** have been further substantially compressed by the compressive pressure applied by the anvil **1040**. It may also be noted upon comparing FIGS. **6C** and **6D** that the first layer **1011** and the third layer **1013** have been further compressed as well. After the staples **1020** have been completely, or at least sufficiently, formed, the anvil **1040** can be lifted away from the tissue **T** and the staple cartridge support **1030** can be moved away, and/or detached from, the staple cartridge **1000**. As depicted in FIG. **6D**, and as a result of the above, the cartridge body **1010** can be implanted with the staples **1020**. In various circumstances, the implanted cartridge body **1010** can support the tissue along the staple line. In some circumstances, a haemostatic agent, and/or any other suitable therapeutic medicament, contained within the implanted cartridge body **1010** can treat the tissue over time. A haemostatic agent, as mentioned above, can reduce the bleeding of the stapled and/or incised tissue while a bonding agent or tissue adhesive can provide strength to the tissue over time. The implanted cartridge body **1010** can be comprised of materials such as ORC (oxidized regenerated cellulose), extracellular proteins such as collagen, polyglycolic acid (PGA) which is marketed under the trade name Vicryl, polylactic acid (PLA or PLLA), polydioxanone (PDS), polyhydroxyalkanoate (PHA), poliglecaprone 25 (PGCL) which is marketed under the trade name Monocryl, polycaprolactone (PCL), and/or a composite of PGA, PLA, PDS, PHA, PGCL and/or PCL, for example. In certain circumstances, the cartridge body **1010** can comprise an antibiotic and/or anti-

microbial material, such as colloidal silver and/or triclosan, for example, which can reduce the possibility of infection in the surgical site.

In various embodiments, the layers of the cartridge body **1010** can be connected to one another. In at least one embodiment, the second layer **1012** can be adhered to the first layer **1011**, the third layer **1013** can be adhered to the second layer **1012**, and the fourth layer **1014** can be adhered to the third layer **1013** utilizing at least one adhesive, such as fibrin and/or protein hydrogel, for example. In certain embodiments, although not illustrated, the layers of the cartridge body **1010** can be connected together by interlocking mechanical features. In at least one such embodiment, the first layer **1011** and the second layer **1012** can each comprise corresponding interlocking features, such as a tongue and groove arrangement and/or a dovetail joint arrangement, for example. Similarly, the second layer **1012** and the third layer **1013** can each comprise corresponding interlocking features while the third layer **1013** and the fourth layer **1014** can each comprise corresponding interlocking features. In certain embodiments, although not illustrated, the staple cartridge **1000** can comprise one or more rivets, for example, which can extend through one or more layers of the cartridge body **1010**. In at least one such embodiment, each rivet can comprise a first end, or head, positioned adjacent to the first layer **1011** and a second head positioned adjacent to the fourth layer **1014** which can be either assembled to or formed by a second end of the rivet. Owing to the compressible nature of the cartridge body **1010**, in at least one embodiment, the rivets can compress the cartridge body **1010** such that the heads of the rivets can be recessed relative to the tissue-contacting surface **1019** and/or the bottom surface **1018** of the cartridge body **1010**, for example. In at least one such embodiment, the rivets can be comprised of a bioabsorbable material, such as polyglycolic acid (PGA) which is marketed under the trade name Vicryl, polylactic acid (PLA or PLLA), polydioxanone (PDS), polyhydroxyalkanoate (PHA), poliglecaprone 25 (PGCL) which is marketed under the trade name Monocryl, polycaprolactone (PCL), and/or a composite of PGA, PLA, PDS, PHA, PGCL and/or PCL, for example. In certain embodiments, the layers of the cartridge body **1010** may not be connected to one another other than by the staples **1020** contained therein. In at least one such embodiment, the frictional engagement between the staple legs **1021** and the cartridge body **1010**, for example, can hold the layers of the cartridge body **1010** together and, once the staples have been formed, the layers can be captured within the staples **1020**. In certain embodiments, at least a portion of the staple legs **1021** can comprise a roughened surface or rough coating which can increase the friction forces between the staples **1020** and the cartridge body **1010**.

As described above, a surgical instrument can comprise a first jaw including the staple cartridge support **1030** and a second jaw including the anvil **1040**. In various embodiments, as described in greater detail further below, the staple cartridge **1000** can comprise one or more retention features which can be configured to engage the staple cartridge support **1030** and, as a result, releasably retain the staple cartridge **1000** to the staple cartridge support **1030**. In certain embodiments, the staple cartridge **1000** can be adhered to the staple cartridge support **1030** by at least one adhesive, such as fibrin and/or protein hydrogel, for example. In use, in at least one circumstance, especially in laparoscopic and/or endoscopic surgery, the second jaw can be moved into a closed position opposite the first jaw, for example, such that the first and second jaws can be inserted through a trocar into a surgical site. In at least one such embodiment, the trocar can define an

approximately 5 mm aperture, or cannula, through which the first and second jaws can be inserted. In certain embodiments, the second jaw can be moved into a partially-closed position intermediate the open position and the closed position which can allow the first and second jaws to be inserted through the trocar without deforming the staples **1020** contained in the staple cartridge body **1010**. In at least one such embodiment, the anvil **1040** may not apply a compressive force to the staple cartridge body **1010** when the second jaw is in its partially-closed intermediate position while, in certain other embodiments, the anvil **1040** can compress the staple cartridge body **1010** when the second jaw is in its partially-closed intermediate position. Even though the anvil **1040** can compress the staple cartridge body **1010** when it is in such an intermediate position, the anvil **1040** may not sufficiently compress the staple cartridge body **1010** such that the anvil **1040** comes into contact with the staples **1020** and/or such that the staples **1020** are deformed by the anvil **1040**. Once the first and second jaws have been inserted through the trocar into the surgical site, the second jaw can be opened once again and the anvil **1040** and the staple cartridge **1000** can be positioned relative to the targeted tissue as described above.

In various embodiments, referring now to FIGS. 7A-7D, an end effector of a surgical stapler can comprise an implantable staple cartridge **1100** positioned intermediate an anvil **1140** and a staple cartridge support **1130**. Similar to the above, the anvil **1140** can comprise a tissue-contacting surface **1141**, the staple cartridge **1100** can comprise a tissue-contacting surface **1119**, and the staple cartridge support **1130** can comprise a support surface **1131** which can be configured to support the staple cartridge **1100**. Referring to FIG. 7A, the anvil **1140** can be utilized to position the tissue T against the tissue contacting surface **1119** of staple cartridge **1100** without deforming the staple cartridge **1100** and, when the anvil **1140** is in such a position, the tissue-contacting surface **1141** can be positioned a distance **1101a** away from the staple cartridge support surface **1131** and the tissue-contacting surface **1119** can be positioned a distance **1102a** away from the staple cartridge support surface **1131**. Thereafter, as the anvil **1140** is moved toward the staple cartridge support **1130**, referring now to FIG. 7B, the anvil **1140** can push the top surface, or tissue-contacting surface **1119**, of staple cartridge **1100** downwardly and compress the first layer **1111** and the second layer **1112** of cartridge body **1110**. As the layers **1111** and **1112** are compressed, referring again to FIG. 7B, the second layer **1112** can be crushed and the legs **1121** of staples **1120** can pierce the first layer **1111** and enter into the tissue T. In at least one such embodiment, the staples **1120** can be at least partially positioned within staple cavities, or voids, **1115** in the second layer **1112** and, when the second layer **1112** is compressed, the staple cavities **1115** can collapse and, as a result, allow the second layer **1112** to collapse around the staples **1120**. In various embodiments, the second layer **1112** can comprise cover portions **1116** which can extend over the staple cavities **1115** and enclose, or at least partially enclose, the staple cavities **1115**. FIG. 7B illustrates the cover portions **1116** being crushed downwardly into the staple cavities **1115**. In certain embodiments, the second layer **1112** can comprise one or more weakened portions which can facilitate the collapse of the second layer **1112**. In various embodiments, such weakened portions can comprise score marks, perforations, and/or thin cross-sections, for example, which can facilitate a controlled collapse of the cartridge body **1110**. In at least one embodiment, the first layer **1111** can comprise one or more weakened portions which can facilitate the penetration of the staple legs **1121** through the first layer **1111**. In various embodiments, such weakened portions can comprise score

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marks, perforations, and/or thin cross-sections, for example, which can be aligned, or at least substantially aligned, with the staple legs **1121**.

When the anvil **1140** is in a partially closed, unfired position, referring again to FIG. 7A, the anvil **1140** can be positioned a distance **1101a** away from the cartridge support surface **1131** such that a gap is defined therebetween. This gap can be filled by the staple cartridge **1100**, having a staple cartridge height **1102a**, and the tissue T. As the anvil **1140** is moved downwardly to compress the staple cartridge **1100**, referring again to FIG. 7B, the distance between the tissue contacting surface **1141** and the cartridge support surface **1131** can be defined by a distance **1101b** which is shorter than the distance **1101a**. In various circumstances, the gap between the tissue-contacting surface **1141** of anvil **1140** and the cartridge support surface **1131**, defined by distance **1101b**, may be larger than the original, undeformed staple cartridge height **1102a**. As the anvil **1140** is moved closer to the cartridge support surface **1131**, referring now to FIG. 7C, the second layer **1112** can continue to collapse and the distance between the staple legs **1121** and the forming pockets **1142** can decrease. Similarly, the distance between the tissue-contacting surface **1141** and the cartridge support surface **1131** can decrease to a distance **1101c** which, in various embodiments, may be greater than, equal to, or less than the original, undeformed cartridge height **1102a**. Referring now to FIG. 7D, the anvil **1140** can be moved into a final, fired position in which the staples **1120** have been fully formed, or at least formed to a desired height. In such a position, the tissue-contacting surface **1141** of anvil **1140** can be a distance **1101d** away from the cartridge support surface **1131**, wherein the distance **1101d** can be shorter than the original, undeformed cartridge height **1102a**. As also illustrated in FIG. 7D, the staple cavities **1115** may be fully, or at least substantially, collapsed and the staples **1120** may be completely, or at least substantially, surrounded by the collapsed second layer **1112**. In various circumstances, the anvil **1140** can be thereafter moved away from the staple cartridge **1100**. Once the anvil **1140** has been disengaged from the staple cartridge **1100**, the cartridge body **1110** can at least partially re-expand in various locations, i.e., locations intermediate adjacent staples **1120**, for example. In at least one embodiment, the crushed cartridge body **1110** may not resiliently re-expand. In various embodiments, the formed staples **1120** and, in addition, the cartridge body **1110** positioned intermediate adjacent staples **1120** may apply pressure, or compressive forces, to the tissue T which may provide various therapeutic benefits.

As discussed above, referring again to the embodiment illustrated in FIG. 7A, each staple **1120** can comprise staple legs **1121** extending therefrom. Although staples **1120** are depicted as comprising two staple legs **1121**, various staples can be utilized which can comprise one staple leg or, alternatively, more than two staple legs, such as three staple legs or four staple legs, for example. As illustrated in FIG. 7A, each staple leg **1121** can be embedded in the second layer **1112** of the cartridge body **1110** such that the staples **1120** are secured within the second layer **1112**. In various embodiments, the staples **1120** can be inserted into the staple cavities **1115** in cartridge body **1110** such that the tips **1123** of the staple legs **1121** enter into the cavities **1115** before the bases **1122**. After the tips **1123** have been inserted into the cavities **1115**, in various embodiments, the tips **1123** can be pressed into the cover portions **1116** and incise the second layer **1112**. In various embodiments, the staples **1120** can be seated to a sufficient depth within the second layer **1112** such that the staples **1120** do not move, or at least substantially move, relative to the second layer **1112**. In certain embodiments, the

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staples **1120** can be seated to a sufficient depth within the second layer **1112** such that the bases **1122** are positioned or embedded within the staple cavities **1115**. In various other embodiments, the bases **1122** may not be positioned or embedded within the second layer **1112**. In certain embodiments, referring again to FIG. 7A, the bases **1122** may extend below the bottom surface **1118** of the cartridge body **1110**. In certain embodiments, the bases **1122** can rest on, or can be directly positioned against, the cartridge support surface **1130**. In various embodiments, the cartridge support surface **1130** can comprise support features extending therefrom and/or defined therein wherein, in at least one such embodiment, the bases **1122** of the staples **1120** may be positioned within and supported by one or more support grooves, slots, or troughs, **1132**, for example, in the staple cartridge support **1130**, as described in greater detail further below.

In various embodiments, referring now to FIGS. 8 and 9, a staple cartridge, such as staple cartridge **1200**, for example, can comprise a compressible, implantable cartridge body **1210** comprising an outer layer **1211** and an inner layer **1212**. Similar to the above, the staple cartridge **1200** can comprise a plurality of staples **1220** positioned within the cartridge body **1210**. In various embodiments, each staple **1220** can comprise a base **1222** and one or more staple legs **1221** extending therefrom. In at least one such embodiment, the staple legs **1221** can be inserted into the inner layer **1212** and seated to a depth in which the bases **1222** of the staples **1220** abut and/or are positioned adjacent to the bottom surface **1218** of the inner layer **1212**, for example. In the embodiment depicted in FIGS. 8 and 9, the inner layer **1212** does not comprise staple cavities configured to receive a portion of the staples **1220** while, in other embodiments, the inner layer **1212** can comprise such staple cavities. In various embodiments, further to the above, the inner layer **1212** can be comprised of a compressible material, such as bioabsorbable foam and/or oxidized regenerated cellulose (ORC), for example, which can be configured to allow the cartridge body **1210** to collapse when a compressive load is applied thereto. In various embodiments, the inner layer **1212** can be comprised of a lyophilized foam comprising polylactic acid (PLA) and/or polyglycolic acid (PGA), for example. The ORC may be commercially available under the trade name Surgicel and can comprise a loose woven fabric (like a surgical sponge), loose fibers (like a cotton ball), and/or a foam. In at least one embodiment, the inner layer **1212** can be comprised of a material including medicaments, such as freeze-dried thrombin and/or fibrin, for example, contained therein and/or coated thereon which can be water-activated and/or activated by fluids within the patient's body, for example. In at least one such embodiment, the freeze-dried thrombin and/or fibrin can be held on a Vicryl (PGA) matrix, for example. In certain circumstances, however, the activatable medicaments can be unintentionally activated when the staple cartridge **1200** is inserted into a surgical site within the patient, for example. In various embodiments, referring again to FIGS. 8 and 9, the outer layer **1211** can be comprised of a water impermeable, or at least substantially water impermeable, material such that liquids do not come into contact with, or at least substantially contact, the inner layer **1212** until after the cartridge body **1210** has been compressed and the staple legs have penetrated the outer layer **1211** and/or after the outer layer **1211** has been incised in some fashion. In various embodiments, the outer layer **1211** can be comprised of a buttress material and/or plastic material, such as polydioxanone (PDS) and/or polyglycolic acid (PGA), for example. In certain embodiments, the outer layer **1211** can comprise a wrap which surrounds the inner layer **1212** and the staples **1220**. More particularly, in at

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least one embodiment, the staples 1220 can be inserted into the inner layer 1212 and the outer layer 1211 can be wrapped around the sub-assembly comprising the inner layer 1212 and the staples 1220 and then sealed.

In various embodiments described herein, the staples of a staple cartridge can be fully formed by an anvil when the anvil is moved into a closed position. In various other embodiments, referring now to FIGS. 10-13, the staples of a staple cartridge, such as staple cartridge 4100, for example, can be deformed by an anvil when the anvil is moved into a closed position and, in addition, by a staple driver system which moves the staples toward the closed anvil. The staple cartridge 4100 can comprise a compressible cartridge body 4110 which can be comprised of a foam material, for example, and a plurality of staples 4120 at least partially positioned within the compressible cartridge body 4110. In various embodiments, the staple driver system can comprise a driver holder 4160, a plurality of staple drivers 4162 positioned within the driver holder 4160, and a staple cartridge pan 4180 which can be configured to retain the staple drivers 4162 in the driver holder 4160. In at least one such embodiment, the staple drivers 4162 can be positioned within one or more slots 4163 in the driver holder 4160 wherein the sidewalls of the slots 4163 can assist in guiding the staple drivers 4162 upwardly toward the anvil. In various embodiments, the staples 4120 can be supported within the slots 4163 by the staple drivers 4162 wherein, in at least one embodiment, the staples 4120 can be entirely positioned in the slots 4163 when the staples 4120 and the staple drivers 4162 are in their unfired positions. In certain other embodiments, at least a portion of the staples 4120 can extend upwardly through the open ends 4161 of slots 4163 when the staples 4120 and staple drivers 4162 are in their unfired positions. In at least one such embodiment, referring primarily now to FIG. 11, the bases of the staples 4120 can be positioned within the driver holder 4160 and the tips of the staples 4120 can be embedded within the compressible cartridge body 4110. In certain embodiments, approximately one-third of the height of the staples 4120 can be positioned within the driver holder 4160 and approximately two-thirds of the height of the staples 4120 can be positioned within the cartridge body 4110. In at least one embodiment, referring to FIG. 10A, the staple cartridge 4100 can further comprise a water impermeable wrap or membrane 4111 surrounding the cartridge body 4110 and the driver holder 4160, for example.

In use, the staple cartridge 4100 can be positioned within a staple cartridge channel, for example, and the anvil can be moved toward the staple cartridge 4100 into a closed position. In various embodiments, the anvil can contact and compress the compressible cartridge body 4110 when the anvil is moved into its closed position. In certain embodiments, the anvil may not contact the staples 4120 when the anvil is in its closed position. In certain other embodiments, the anvil may contact the legs of the staples 4120 and at least partially deform the staples 4120 when the anvil is moved into its closed position. In either event, the staple cartridge 4100 can further comprise one or more sleds 4170 which can be advanced longitudinally within the staple cartridge 4100 such that the sleds 4170 can sequentially engage the staple drivers 4162 and move the staple drivers 4162 and the staples 4120 toward the anvil. In various embodiments, the sleds 4170 can slide between the staple cartridge pan 4180 and the staple drivers 4162. In embodiments where the closure of the anvil has started the forming process of the staples 4120, the upward movement of the staples 4120 toward the anvil can complete the forming process and deform the staples 4120 to their fully formed, or at least desired, height. In embodiments

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where the closure of the anvil has not deformed the staples 4120, the upward movement of the staples 4120 toward the anvil can initiate and complete the forming process and deform the staples 4120 to their fully formed, or at least desired, height. In various embodiments, the sleds 4170 can be advanced from a proximal end of the staple cartridge 4100 to a distal end of the staple cartridge 4100 such that the staples 4120 positioned in the proximal end of the staple cartridge 4100 are fully formed before the staples 4120 positioned in the distal end of the staple cartridge 4100 are fully formed. In at least one embodiment, referring to FIG. 12, the sleds 4170 can each comprise at least one angled or inclined surface 4711 which can be configured to slide underneath the staple drivers 4162 and lift the staple drivers 4162 as illustrated in FIG. 13.

In various embodiments, further to the above, the staples 4120 can be formed in order to capture at least a portion of the tissue T and at least a portion of the compressible cartridge body 4110 of the staple cartridge 4100 therein. After the staples 4120 have been formed, the anvil and the staple cartridge channel 4130 of the surgical stapler can be moved away from the implanted staple cartridge 4100. In various circumstances, the cartridge pan 4180 can be fixedly engaged with the staple cartridge channel 4130 wherein, as a result, the cartridge pan 4180 can become detached from the compressible cartridge body 4110 as the staple cartridge channel 4130 is pulled away from the implanted cartridge body 4110. In various embodiments, referring again to FIG. 10, the cartridge pan 4180 can comprise opposing side walls 4181 between which the cartridge body 4110 can be removably positioned. In at least one such embodiment, the compressible cartridge body 4110 can be compressed between the side walls 4181 such that the cartridge body 4110 can be removably retained therebetween during use and releasably disengaged from the cartridge pan 4180 as the cartridge pan 4180 is pulled away. In at least one such embodiment, the driver holder 4160 can be connected to the cartridge pan 4180 such that the driver holder 4160, the drivers 4162, and/or the sleds 4170 can remain in the cartridge pan 4180 when the cartridge pan 4180 is removed from the surgical site. In certain other embodiments, the drivers 4162 can be ejected from the driver holder 4160 and left within the surgical site. In at least one such embodiment, the drivers 4162 can be comprised of a bioabsorbable material, such as polyglycolic acid (PGA) which is marketed under the trade name Vicryl, polylactic acid (PLA or PLLA), polydioxanone (PDS), polyhydroxyalkanoate (PHA), poliglecaprone 25 (PGCL) which is marketed under the trade name Monocryl, polycaprolactone (PCL), and/or a composite of PGA, PLA, PDS, PHA, PGCL and/or PCL, for example. In various embodiments, the drivers 4162 can be attached to the staples 4120 such that the drivers 4162 are deployed with the staples 4120. In at least one such embodiment, each driver 4162 can comprise a trough configured to receive the bases of the staples 4120, for example, wherein, in at least one embodiment, the troughs can be configured to receive the staple bases in a press-fit and/or snap-fit manner.

In certain embodiments, further to the above, the driver holder 4160 and/or the sleds 4170 can be ejected from the cartridge pan 4180. In at least one such embodiment, the sleds 4170 can slide between the cartridge pan 4180 and the driver holder 4160 such that, as the sleds 4170 are advanced in order to drive the staple drivers 4162 and staples 4120 upwardly, the sleds 4170 can move the driver holder 4160 upwardly out of the cartridge pan 4180 as well. In at least one such embodiment, the driver holder 4160 and/or the sleds 4170 can be comprised of a bioabsorbable material, such as polyglycolic acid (PGA) which is marketed under the trade name Vicryl,

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polylactic acid (PLA or PLLA), polydioxanone (PDS), polyhydroxyalkanoate (PHA), poliglecaprone 25 (PGCL) which is marketed under the trade name Monocryl, polycaprolactone (PCL), and/or a composite of PGA, PLA, PDS, PHA, PGCL and/or PCL, for example. In various embodiments, the sleds 4170 can be integrally formed and/or attached to a drive bar, or cutting member, which pushes the sleds 4170 through the staple cartridge 4100. In such embodiments, the sleds 4170 may not be ejected from the cartridge pan 4180 and may remain with the surgical stapler while, in other embodiments in which the sleds 4170 are not attached to the drive bar, the sleds 4170 may be left in the surgical site. In any event, further to the above, the compressibility of the cartridge body 4110 can allow thicker staple cartridges to be used within an end effector of a surgical stapler as the cartridge body 4110 can compress, or shrink, when the anvil of the stapler is closed. In certain embodiments, as a result of the staples being at least partially deformed upon the closure of the anvil, taller staples, such as staples having an approximately 0.18" staple height, for example, could be used, wherein approximately 0.12" of the staple height can be positioned within the compressible layer 4110 and wherein the compressible layer 4110 can have an uncompressed height of approximately 0.14", for example.

In many embodiments described herein, a staple cartridge can comprise a plurality of staples therein. In various embodiments, such staples can be comprised of a metal wire deformed into a substantially U-shaped configuration having two staple legs. Other embodiments are envisioned in which staples can comprise different configurations such as two or more wires that have been joined together having three or more staple legs. In various embodiments, the wire, or wires, used to form the staples can comprise a round, or at least substantially round, cross-section. In at least one embodiment, the staple wires can comprise any other suitable cross-section, such as square and/or rectangular cross-sections, for example. In certain embodiments, the staples can be comprised of plastic wires. In at least one embodiment, the staples can be comprised of plastic-coated metal wires. In various embodiments, a cartridge can comprise any suitable type of fastener in addition to or in lieu of staples. In at least one such embodiment, such a fastener can comprise pivotable arms which are folded when engaged by an anvil. In certain embodiments, two-part fasteners could be utilized. In at least one such embodiment, a staple cartridge can comprise a plurality of first fastener portions and an anvil can comprise a plurality of second fastener portions which are connected to the first fastener portions when the anvil is compressed against the staple cartridge. In certain embodiments, as described above, a sled or driver can be advanced within a staple cartridge in order to complete the forming process of the staples. In certain embodiments, a sled or driver can be advanced within an anvil in order to move one or more forming members downwardly into engagement with the opposing staple cartridge and the staples, or fasteners, positioned therein.

In various embodiments described herein, a staple cartridge can comprise four rows of staples stored therein. In at least one embodiment, the four staple rows can be arranged in two inner staple rows and two outer staple rows. In at least one such embodiment, an inner staple row and an outer staple row can be positioned on a first side of a cutting member, or knife, slot within the staple cartridge and, similarly, an inner staple row and an outer staple row can be positioned on a second side of the cutting member, or knife, slot. In certain embodiments, a staple cartridge may not comprise a cutting member slot; however, such a staple cartridge may comprise a designated

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portion configured to be incised by a cutting member in lieu of a staple cartridge slot. In various embodiments, the inner staple rows can be arranged within the staple cartridge such that they are equally, or at least substantially equally, spaced from the cutting member slot. Similarly, the outer staple rows can be arranged within the staple cartridge such that they are equally, or at least substantially equally, spaced from the cutting member slot. In various embodiments, a staple cartridge can comprise more than or less than four rows of staples stored within a staple cartridge. In at least one embodiment, a staple cartridge can comprise six rows of staples. In at least one such embodiment, the staple cartridge can comprise three rows of staples on a first side of a cutting member slot and three rows of staples on a second side of the cutting member slot. In certain embodiments, a staple cartridge may comprise an odd number of staple rows. For example, a staple cartridge may comprise two rows of staples on a first side of a cutting member slot and three rows of staples on a second side of the cutting member slot. In various embodiments, the staple rows can comprise staples having the same, or at least substantially the same, unformed staple height. In certain other embodiments, one or more of the staple rows can comprise staples having a different unformed staple height than the other staples. In at least one such embodiment, the staples on a first side of a cutting member slot may have a first unformed height and the staples on a second side of a cutting member slot may have a second unformed height which is different than the first height, for example.

In various embodiments, as described above, a staple cartridge can comprise a cartridge body including a plurality of staple cavities defined therein. The cartridge body can comprise a deck and a top deck surface wherein each staple cavity can define an opening in the deck surface. As also described above, a staple can be positioned within each staple cavity such that the staples are stored within the cartridge body until they are ejected therefrom. Prior to being ejected from the cartridge body, in various embodiments, the staples can be contained with the cartridge body such that the staples do not protrude above the deck surface. As the staples are positioned below the deck surface, in such embodiments, the possibility of the staples becoming damaged and/or prematurely contacting the targeted tissue can be reduced. In various circumstances, the staples can be moved between an unfired position in which they do not protrude from the cartridge body and a fired position in which they have emerged from the cartridge body and can contact an anvil positioned opposite the staple cartridge. In various embodiments, the anvil, and/or the forming pockets defined within the anvil, can be positioned a predetermined distance above the deck surface such that, as the staples are being deployed from the cartridge body, the staples are deformed to a predetermined formed height. In some circumstances, the thickness of the tissue captured between the anvil and the staple cartridge may vary and, as a result, thicker tissue may be captured within certain staples while thinner tissue may be captured within certain other staples. In either event, the clamping pressure, or force, applied to the tissue by the staples may vary from staple to staple or vary between a staple on one end of a staple row and a staple on the other end of the staple row, for example. In certain circumstances, the gap between the anvil and the staple cartridge deck can be controlled such that the staples apply a certain minimum clamping pressure within each staple. In some such circumstances, however, significant variation of the clamping pressure within different staples may still exist. Surgical stapling instruments are disclosed in U.S. Pat. No. 7,380,696, which issued on Jun. 3, 2008, the entire disclosure of which is incorporated by reference herein.

An illustrative multi-stroke handle for the surgical stapling and severing instrument is described in greater detail in the co-pending and co-owned U.S. patent application entitled SURGICAL STAPLING INSTRUMENT INCORPORATING A MULTISTROKE FIRING POSITION INDICATOR AND RETRACTION MECHANISM, Ser. No. 10/674,026, the disclosure of which is hereby incorporated by reference in its entirety. Other applications consistent with the present invention may incorporate a single firing stroke, such as described in co-pending and commonly owned U.S. patent application SURGICAL STAPLING INSTRUMENT HAVING SEPARATE DISTINCT CLOSING AND FIRING SYSTEMS, Ser. No. 10/441,632, the disclosure of which is hereby incorporated by reference in its entirety.

In various embodiments described herein, a staple cartridge can comprise means for compensating for the thickness of the tissue captured within the staples deployed from the staple cartridge. In various embodiments, referring to FIG. 14, a staple cartridge, such as staple cartridge 10000, for example, can include a rigid first portion, such as support portion 10010, for example, and a compressible second portion, such as tissue thickness compensator 10020, for example. In at least one embodiment, referring primarily to FIG. 16, the support portion 10010 can comprise a cartridge body, a top deck surface 10011, and a plurality of staple cavities 10012 wherein, similar to the above, each staple cavity 10012 can define an opening in the deck surface 10011. A staple 10030, for example, can be removably positioned in each staple cavity 10012. In at least one such embodiment, each staple 10030 can comprise a base 10031 and one or more legs 10032 extending from the base 10031. Prior to the staples 10030 being deployed, as also described in greater detail below, the bases 10031 of the staples 10030 can be supported by staple drivers positioned within the support portion 10010 and, concurrently, the legs 10032 of the staples 10030 can be at least partially contained within the staple cavities 10012. In various embodiments, the staples 10030 can be deployed between an unfired position and a fired position such that the legs 10032 move through the tissue thickness compensator 10020, penetrate through a top surface of the tissue thickness compensator 10020, penetrate the tissue T, and contact an anvil positioned opposite the staple cartridge 10000. As the legs 10032 are deformed against the anvil, the legs 10032 of each staple 10030 can capture a portion of the tissue thickness compensator 10020 and a portion of the tissue T within each staple 10030 and apply a compressive force to the tissue. Further to the above, the legs 10032 of each staple 10030 can be deformed downwardly toward the base 10031 of the staple to form a staple entrapment area 10039 in which the tissue T and the tissue thickness compensator 10020 can be captured. In various circumstances, the staple entrapment area 10039 can be defined between the inner surfaces of the deformed legs 10032 and the inner surface of the base 10031. The size of the entrapment area for a staple can depend on several factors such as the length of the legs, the diameter of the legs, the width of the base, and/or the extent in which the legs are deformed, for example.

In previous embodiments, a surgeon was often required to select the appropriate staples having the appropriate staple height for the tissue being stapled. For example, a surgeon could select tall staples for use with thick tissue and short staples for use with thin tissue. In some circumstances, however, the tissue being stapled did not have a consistent thickness and, thus, some staples were unable to achieve the desired fired configuration. For example, FIG. 48 illustrates a tall staple used in thin tissue. Referring now to FIG. 49, when a tissue thickness compensator, such as tissue thickness com-

pensator 10020, for example, is used with thin tissue, for example, the larger staple may be formed to a desired fired configuration.

Owing to the compressibility of the tissue thickness compensator, the tissue thickness compensator can compensate for the thickness of the tissue captured within each staple. More particularly, referring now to FIGS. 43 and 44, a tissue thickness compensator, such as tissue thickness compensator 10020, for example, can consume larger and/or smaller portions of the staple entrapment area 10039 of each staple 10030 depending on the thickness and/or type of tissue contained within the staple entrapment area 10039. For example, if thinner tissue T is captured within a staple 10030, the tissue thickness compensator 10020 can consume a larger portion of the staple entrapment area 10039 as compared to circumstances where thicker tissue T is captured within the staple 10030. Correspondingly, if thicker tissue T is captured within a staple 10030, the tissue thickness compensator 10020 can consume a smaller portion of the staple entrapment area 10039 as compared to the circumstances where thinner tissue T is captured within the staple 10030. In this way, the tissue thickness compensator can compensate for thinner tissue and/or thicker tissue and assure that a compressive pressure is applied to the tissue irrespective, or at least substantially irrespective, of the tissue thickness captured within the staples. In addition to the above, the tissue thickness compensator 10020 can compensate for different types, or compressibilities, of tissues captured within different staples 10030. Referring now to FIG. 44, the tissue thickness compensator 10020 can apply a compressive force to vascular tissue T which can include vessels V and, as a result, restrict the flow of blood through the less compressible vessels V while still applying a desired compressive pressure to the surrounding tissue T. In various circumstances, further to the above, the tissue thickness compensator 10020 can also compensate for malformed staples. Referring to FIG. 45, the malformation of various staples 10030 can result in larger staple entrapment areas 10039 being defined within such staples. Owing to the resiliency of the tissue thickness compensator 10020, referring now to FIG. 46, the tissue thickness compensator 10020 positioned within malformed staples 10030 may still apply a sufficient compressive pressure to the tissue T even though the staple entrapment areas 10039 defined within such malformed staples 10030 may be enlarged. In various circumstances, the tissue thickness compensator 10020 located intermediate adjacent staples 10030 can be biased against the tissue T by properly-formed staples 10030 surrounding a malformed staple 10030 and, as a result, apply a compressive pressure to the tissue surrounding and/or captured within the malformed staple 10030, for example. In various circumstances, a tissue thickness compensator can compensate for different tissue densities which can arise due to calcifications, fibrous areas, and/or tissue that has been previously stapled or treated, for example.

In various embodiments, a fixed, or unchangeable, tissue gap can be defined between the support portion and the anvil and, as a result, the staples may be deformed to a predetermined height regardless of the thickness of the tissue captured within the staples. When a tissue thickness compensator is used with these embodiments, the tissue thickness compensator can adapt to the tissue captured between the anvil and the support portion staple cartridge and, owing to the resiliency of the tissue thickness compensator, the tissue thickness compensator can apply an additional compressive pressure to the tissue. Referring now to FIGS. 50-55, a staple 10030 has been formed to a predefined height H. With regard to FIG. 50, a tissue thickness compensator has not been utilized and the

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tissue T consumes the entirety of the staple entrapment area **10039**. With regard to FIG. **57**, a portion of a tissue thickness compensator **10020** has been captured within the staple **10030**, compressed the tissue T, and consumed at least a portion of the staple entrapment area **10039**. Referring now to FIG. **52**, thin tissue T has been captured within the staple **10030**. In this embodiment, the compressed tissue T has a height of approximately  $2/9H$  and the compressed tissue thickness compensator **10020** has a height of approximately  $7/9H$ , for example. Referring now to FIG. **53**, tissue T having an intermediate thickness has been captured within the staple **10030**. In this embodiment, the compressed tissue T has a height of approximately  $4/9H$  and the compressed tissue thickness compensator **10020** has a height of approximately  $5/9H$ , for example. Referring now to FIG. **54**, tissue T having an intermediate thickness has been captured within the staple **10030**. In this embodiment, the compressed tissue T has a height of approximately  $2/3H$  and the compressed tissue thickness compensator **10020** has a height of approximately  $1/3H$ , for example. Referring now to FIG. **53**, thick tissue T has been captured within the staple **10030**. In this embodiment, the compressed tissue T has a height of approximately  $8/9H$  and the compressed tissue thickness compensator **10020** has a height of approximately  $1/9H$ , for example. In various circumstances, the tissue thickness compensator can comprise a compressed height which comprises approximately 10% of the staple entrapment height, approximately 20% of the staple entrapment height, approximately 30% of the staple entrapment height, approximately 40% of the staple entrapment height, approximately 50% of the staple entrapment height, approximately 60% of the staple entrapment height, approximately 70% of the staple entrapment height, approximately 80% of the staple entrapment height, and/or approximately 90% of the staple entrapment height, for example.

In various embodiments, the staples **10030** can comprise any suitable unformed height. In certain embodiments, the staples **10030** can comprise an unformed height between approximately 2 mm and approximately 4.8 mm, for example. The staples **10030** can comprise an unformed height of approximately 2.0 mm, approximately 2.5 mm, approximately 3.0 mm, approximately 3.4 mm, approximately 3.5 mm, approximately 3.8 mm, approximately 4.0 mm, approximately 4.1 mm, and/or approximately 4.8 mm, for example. In various embodiments, the height H to which the staples can be deformed can be dictated by the distance between the deck surface **10011** of the support portion **10010** and the opposing anvil. In at least one embodiment, the distance between the deck surface **10011** and the tissue-contacting surface of the anvil can be approximately 0.097", for example. The height H can also be dictated by the depth of the forming pockets defined within the anvil. In at least one embodiment, the forming pockets can have a depth measured from the tissue-contacting surface, for example. In various embodiments, as described in greater detail below, the staple cartridge **10000** can further comprise staple drivers which can lift the staples **10030** toward the anvil and, in at least one embodiment, lift, or "overdrive", the staples above the deck surface **10011**. In such embodiments, the height H to which the staples **10030** are formed can also be dictated by the distance in which the staples **10030** are overdriven. In at least one such embodiment, the staples **10030** can be overdriven by approximately 0.028", for example, and can result in the staples **10030** being formed to a height of approximately 0.189", for example. In various embodiments, the staples **10030** can be formed to a height of approximately 0.8 mm, approximately 1.0 mm, approximately 1.5 mm, approximately 1.8 mm, approxi-

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mately 2.0 mm, and/or approximately 2.25 mm, for example. In certain embodiments, the staples can be formed to a height between approximately 2.25 mm and approximately 3.0 mm, for example. Further to the above, the height of the staple entrapment area of a staple can be determined by the formed height of the staple and the width, or diameter, of the wire comprising the staple. In various embodiments, the height of the staple entrapment area **10039** of a staple **10030** can comprise the formed height H of the staple less two diameter widths of the wire. In certain embodiments, the staple wire can comprise a diameter of approximately 0.0089", for example. In various embodiments, the staple wire can comprise a diameter between approximately 0.0069" and approximately 0.0119", for example. In at least one exemplary embodiment, the formed height H of a staple **10030** can be approximately 0.189" and the staple wire diameter can be approximately 0.0089" resulting in a staple entrapment height of approximately 0.171", for example.

In various embodiments, further to the above, the tissue thickness compensator can comprise an uncompressed, or pre-deployed, height and can be configured to deform to one of a plurality of compressed heights. In certain embodiments, the tissue thickness compensator can comprise an uncompressed height of approximately 0.125", for example. In various embodiments, the tissue thickness compensator can comprise an uncompressed height of greater than or equal to approximately 0.080", for example. In at least one embodiment, the tissue thickness compensator can comprise an uncompressed, or pre-deployed, height which is greater than the unfired height of the staples. In at least one embodiment, the uncompressed, or pre-deployed, height of the tissue thickness compensator can be approximately 10% taller, approximately 20% taller, approximately 30% taller, approximately 40% taller, approximately 50% taller, approximately 60% taller, approximately 70% taller, approximately 80% taller, approximately 90% taller, and/or approximately 100% taller than the unfired height of the staples, for example. In at least one embodiment, the uncompressed, or pre-deployed, height of the tissue thickness compensator can be up to approximately 100% taller than the unfired height of the staples, for example. In certain embodiments, the uncompressed, or pre-deployed, height of the tissue thickness compensator can be over 100% taller than the unfired height of the staples, for example. In at least one embodiment, the tissue thickness compensator can comprise an uncompressed height which is equal to the unfired height of the staples. In at least one embodiment, the tissue thickness compensator can comprise an uncompressed height which is less than the unfired height of the staples. In at least one embodiment, the uncompressed, or pre-deployed, height of the thickness compensator can be approximately 10% shorter, approximately 20% shorter, approximately 30% shorter, approximately 40% shorter, approximately 50% shorter, approximately 60% shorter, approximately 70% shorter, approximately 80% shorter, and/or approximately 90% shorter than the unfired height of the staples, for example. In various embodiments, the compressible second portion can comprise an uncompressed height which is taller than an uncompressed height of the tissue T being stapled. In certain embodiments, the tissue thickness compensator can comprise an uncompressed height which is equal to an uncompressed height of the tissue T being stapled. In various embodiments, the tissue thickness compensator can comprise an uncompressed height which is shorter than an uncompressed height of the tissue T being stapled.

As described above, a tissue thickness compensator can be compressed within a plurality of formed staples regardless of whether thick tissue or thin tissue is captured within the



staples. In at least one exemplary embodiment, the staples within a staple line, or row, can be deformed such that the staple entrapment area of each staple comprises a height of approximately 2.0 mm, for example, wherein the tissue T and the tissue thickness compensator can be compressed within this height. In certain circumstances, the tissue T can comprise a compressed height of approximately 1.75 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 0.25 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example. In certain circumstances, the tissue T can comprise a compressed height of approximately 1.50 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 0.50 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example. In certain circumstances, the tissue T can comprise a compressed height of approximately 1.25 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 0.75 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example. In certain circumstances, the tissue T can comprise a compressed height of approximately 1.0 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 1.0 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example. In certain circumstances, the tissue T can comprise a compressed height of approximately 0.75 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 1.25 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example. In certain circumstances, the tissue T can comprise a compressed height of approximately 1.50 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 0.50 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example. In certain circumstances, the tissue T can comprise a compressed height of approximately 0.25 mm within the staple entrapment area while the tissue thickness compensator can comprise a compressed height of approximately 1.75 mm within the staple entrapment area, thereby totaling the approximately 2.0 mm staple entrapment area height, for example.

In various embodiments, further to the above, the tissue thickness compensator can comprise an uncompressed height which is less than the fired height of the staples. In certain embodiments, the tissue thickness compensator can comprise an uncompressed height which is equal to the fired height of the staples. In certain other embodiments, the tissue thickness compensator can comprise an uncompressed height which is taller than the fired height of the staples. In at least one such embodiment, the uncompressed height of a tissue thickness compensator can comprise a thickness which is approximately 110% of the formed staple height, approximately 120% of the formed staple height, approximately 130% of the formed staple height, approximately 140% of the formed staple height, approximately 150% of the formed staple height, approximately 160% of the formed staple height, approximately 170% of the formed staple height, approximately 180% of the formed staple height, approximately 190% of the formed staple height, and/or approximately 200% of the formed staple height, for example. In certain

embodiments, the tissue thickness compensator can comprise an uncompressed height which is more than twice the fired height of the staples. In various embodiments, the tissue thickness compensator can comprise a compressed height which is from approximately 85% to approximately 150% of the formed staple height, for example. In various embodiments, as described above, the tissue thickness compensator can be compressed between an uncompressed thickness and a compressed thickness. In certain embodiments, the compressed thickness of a tissue thickness compensator can be approximately 10% of its uncompressed thickness, approximately 20% of its uncompressed thickness, approximately 30% of its uncompressed thickness, approximately 40% of its uncompressed thickness, approximately 50% of its uncompressed thickness, approximately 60% of its uncompressed thickness, approximately 70% of its uncompressed thickness, approximately 80% of its uncompressed thickness, and/or approximately 90% of its uncompressed thickness, for example. In various embodiments, the uncompressed thickness of the tissue thickness compensator can be approximately two times, approximately ten times, approximately fifty times, and/or approximately one hundred times thicker than its compressed thickness, for example. In at least one embodiment, the compressed thickness of the tissue thickness compensator can be between approximately 60% and approximately 99% of its uncompressed thickness. In at least one embodiment, the uncompressed thickness of the tissue thickness compensator can be at least 50% thicker than its compressed thickness. In at least one embodiment, the uncompressed thickness of the tissue thickness compensator can be up to one hundred times thicker than its compressed thickness. In various embodiments, the compressible second portion can be elastic, or at least partially elastic, and can bias the tissue T against the deformed legs of the staples. In at least one such embodiment, the compressible second portion can resiliently expand between the tissue T and the base of the staple in order to push the tissue T against the legs of the staple. In certain embodiments, discussed in further detail below, the tissue thickness compensator can be positioned intermediate the tissue T and the deformed staple legs. In various circumstances, as a result of the above, the tissue thickness compensator can be configured to consume any gaps within the staple entrapment area.

In various embodiments, the tissue thickness compensator may comprise materials characterized by one or more of the following properties: biocompatible, bioabsorbable, bioreabsorbable, biodurable, biodegradable, compressible, fluid absorbable, swellable, self-expandable, bioactive, medicament, pharmaceutically active, anti-adhesion, haemostatic, antibiotic, anti-microbial, anti-viral, nutritional, adhesive, permeable, hydrophilic and/or hydrophobic, for example. In various embodiments, a surgical instrument comprising an anvil and a staple cartridge may comprise a tissue thickness compensator associated with the anvil and/or staple cartridge comprising at least one of a haemostatic agent, such as fibrin and thrombin, an antibiotic, such as doxycycline, and medicament, such as matrix metalloproteinases (MMPs).

In various embodiments, the tissue thickness compensator may comprise synthetic and/or non-synthetic materials. The tissue thickness compensator may comprise a polymeric composition comprising one or more synthetic polymers and/or one or more non-synthetic polymers. The synthetic polymer may comprise a synthetic absorbable polymer and/or a synthetic non-absorbable polymer. In various embodiments, the polymeric composition may comprise a biocompatible foam, for example. The biocompatible foam may comprise a porous, open cell foam and/or a porous, closed cell foam, for



example. The biocompatible foam may have a uniform pore morphology or may have a gradient pore morphology (i.e. small pores gradually increasing in size to large pores across the thickness of the foam in one direction). In various embodiments, the polymeric composition may comprise one or more of a porous scaffold, a porous matrix, a gel matrix, a hydrogel matrix, a solution matrix, a filamentous matrix, a tubular matrix, a composite matrix, a membranous matrix, a biostable polymer, and a biodegradable polymer, and combinations thereof. For example, the tissue thickness compensator may comprise a foam reinforced by a filamentous matrix or may comprise a foam having an additional hydrogel layer that expands in the presence of bodily fluids to further provide the compression on the tissue. In various embodiments, a tissue thickness compensator could also be comprised of a coating on a material and/or a second or third layer that expands in the presence of bodily fluids to further provide the compression on the tissue. Such a layer could be a hydrogel that could be a synthetic and/or naturally derived material and could be either biodurable and/or biodegradable, for example. In various embodiments, the tissue thickness compensator may comprise a microgel or a nanogel. The hydrogel may comprise carbohydrate-derived microgels and/or nanogels. In certain embodiments, a tissue thickness compensator may be reinforced with fibrous non-woven materials or fibrous mesh type elements, for example, that can provide additional flexibility, stiffness, and/or strength. In various embodiments, a tissue thickness compensator that has a porous morphology which exhibits a gradient structure such as, for example, small pores on one surface and larger pores on the other surface. Such morphology could be more optimal for tissue in-growth or haemostatic behavior. Further, the gradient could be also compositional with a varying bio-absorption profile. A short term absorption profile may be preferred to address hemostasis while a long term absorption profile may address better tissue healing without leakages.

Examples of non-synthetic materials include, but are not limited to, lyophilized polysaccharide, glycoprotein, bovine pericardium, collagen, gelatin, fibrin, fibrinogen, elastin, proteoglycan, keratin, albumin, hydroxyethyl cellulose, cellulose, oxidized cellulose, oxidized regenerated cellulose (ORC), hydroxypropyl cellulose, carboxyethyl cellulose, carboxymethylcellulose, chitan, chitosan, casein, alginate, and combinations thereof.

Examples of synthetic absorbable materials include, but are not limited to, poly(lactic acid) (PLA), poly(L-lactic acid) (PLLA), polycaprolactone (PCL), polyglycolic acid (PGA), poly(trimethylene carbonate) (TMC), polyethylene terephthalate (PET), polyhydroxyalkanoate (PHA), a copolymer of glycolide and  $\epsilon$ -caprolactone (PGCL), a copolymer of glycolide and trimethylene carbonate, poly(glycerol sebacate) (PGS), poly(dioxanone) (PDS), polyesters, poly(orthoesters), polyoxaesters, polyetheresters, polycarbonates, polyamide esters, polyanhydrides, polysaccharides, poly(esteramides), tyrosine-based polyarylates, polyamines, tyrosine-based polyiminocarbonates, tyrosine-based polycarbonates, poly(D,L-lactide-urethane), poly(hydroxybutyrate), poly(B-hydroxybutyrate), poly( $\epsilon$ -caprolactone), polyethyleneglycol (PEG), poly[bis(carboxylatophenoxy)phosphazene]poly(amino acids), pseudo-poly(amino acids), absorbable polyurethanes, poly(phosphazine), polyphosphazenes, polyalkyleneoxides, polyacrylamides, polyhydroxyethylmethacrylate, polyvinylpyrrolidone, polyvinyl alcohols, poly(caprolactone), polyacrylic acid, polyacetate, polypropylene, aliphatic polyesters, glycerols, copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), polyalkylene oxalates, and combina-

tions thereof. In various embodiments, the polyester may be selected from the group consisting of polylactides, polyglycolides, trimethylene carbonates, polydioxanones, polycaprolactones, polybutesters, and combinations thereof.

In various embodiments, the synthetic absorbable polymer may comprise one or more of 90/10 poly(glycolide-L-lactide) copolymer, commercially available from Ethicon, Inc. under the trade designation VICRYL (polyglactin 910), polyglycolide, commercially available from American Cyanamid Co. under the trade designation DEXON, polydioxanone, commercially available from Ethicon, Inc. under the trade designation PDS, poly(glycolide-trimethylene carbonate) random block copolymer, commercially available from American Cyanamid Co. under the trade designation MAXON, 75/25 poly(glycolide- $\epsilon$ -caprolactone-poliglecaprolactone 25) copolymer, commercially available from Ethicon under the trade designation MONOCRYL, for example.

Examples of synthetic non-absorbable materials include, but are not limited to, polyurethane, polypropylene (PP), polyethylene (PE), polycarbonate, polyamides, such as nylon, polyvinylchloride (PVC), polymethylmethacrylate (PMMA), polystyrene (PS), polyester, polyetheretherketone (PEEK), polytetrafluoroethylene (PTFE), polytrifluoroethylene (PTFCE), polyvinylfluoride (PVF), fluorinated ethylene propylene (FEP), polyacetal, polysulfone, silicones, and combinations thereof. The synthetic non-absorbable polymers may include, but are not limited to, foamed elastomers and porous elastomers, such as, for example, silicone, polyisoprene, and rubber. In various embodiments, the synthetic polymers may comprise expanded polytetrafluoroethylene (ePTFE), commercially available from W. L. Gore & Associates, Inc. under the trade designation GORE-TEX Soft Tissue Patch and co-polyetherester urethane foam commercially available from Polyganics under the trade designation NASOPORE.

In various embodiments, the polymeric composition may comprise from approximately 50% to approximately 90% by weight of the polymeric composition of PLLA and approximately 50% to approximately 10% by weight of the polymeric composition of PCL, for example. In at least one embodiment, the polymeric composition may comprise approximately 70% by weight of PLLA and approximately 30% by weight of PCL, for example. In various embodiments, the polymeric composition may comprise from approximately 55% to approximately 85% by weight of the polymeric composition of PGA and 15% to 45% by weight of the polymeric composition of PCL, for example. In at least one embodiment, the polymeric composition may comprise approximately 65% by weight of PGA and approximately 35% by weight of PCL, for example. In various embodiments, the polymeric composition may comprise from approximately 90% to approximately 95% by weight of the polymeric composition of PGA and approximately 5% to approximately 10% by weight of the polymeric composition of PLA, for example.

In various embodiments, the synthetic absorbable polymer may comprise a bioabsorbable, biocompatible elastomeric copolymer. Suitable bioabsorbable, biocompatible elastomeric copolymers include but are not limited to copolymers of  $\epsilon$ -caprolactone and glycolide (preferably having a mole ratio of  $\epsilon$ -caprolactone to glycolide of from about 30:70 to about 70:30, preferably 35:65 to about 65:35, and more preferably 45:55 to 35:65); elastomeric copolymers of  $\epsilon$ -caprolactone and lactide, including L-lactide, D-lactide blends thereof or lactic acid copolymers (preferably having a mole ratio of  $\epsilon$ -caprolactone to lactide of from about 35:65 to about 65:35 and more preferably 45:55 to 30:70) elastomeric

copolymers of p-dioxanone (1,4-dioxan-2-one) and lactide including L-lactide, D-lactide and lactic acid (preferably having a mole ratio of p-dioxanone to lactide of from about 40:60 to about 60:40); elastomeric copolymers of  $\epsilon$ -caprolactone and p-dioxanone (preferably having a mole ratio of  $\epsilon$ -caprolactone to p-dioxanone of from about 30:70 to about 70:30); elastomeric copolymers of p-dioxanone and trimethylene carbonate (preferably having a mole ratio of p-dioxanone to trimethylene carbonate of from about 30:70 to about 70:30); elastomeric copolymers of trimethylene carbonate and glycolide (preferably having a mole ratio of trimethylene carbonate to glycolide of from about 30:70 to about 70:30); elastomeric copolymer of trimethylene carbonate and lactide including L-lactide, D-lactide, blends thereof or lactic acid copolymers (preferably having a mole ratio of trimethylene carbonate to lactide of from about 30:70 to about 70:30) and blends thereof. In one embodiment, the elastomeric copolymer is a copolymer of glycolide and  $\epsilon$ -caprolactone. In another embodiment, the elastomeric copolymer is a copolymer of lactide and  $\epsilon$ -caprolactone.

The disclosures of U.S. Pat. No. 5,468,253, entitled ELASTOMERIC MEDICAL DEVICE, which issued on Nov. 21, 1995, and U.S. Pat. No. 6,325,810, entitled FOAM BUTTRESS FOR STAPLING APPARATUS, which issued on Dec. 4, 2001, are hereby incorporated by reference in their respective entireties.

In various embodiments, the tissue thickness compensator may comprise an emulsifier. Examples of emulsifiers may include, but are not limited to, water-soluble polymers, such as, polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP), polyethylene glycol (PEG), polypropylene glycol (PPG), PLURONICS, TWEENS, polysaccharides and combinations thereof.

In various embodiments, the tissue thickness compensator may comprise a surfactant. Examples of surfactants may include, but are not limited to, polyacrylic acid, methalose, methyl cellulose, ethyl cellulose, propyl cellulose, hydroxy ethyl cellulose, carboxy methyl cellulose, polyoxyethylene cetyl ether, polyoxyethylene lauryl ether, polyoxyethylene octyl ether, polyoxyethylene octylphenyl ether, polyoxyethylene oleyl ether, polyoxyethylene sorbitan monolaurate, polyoxyethylene stearyl ether, polyoxyethylene nonylphenyl ether, dialkylphenoxy poly(ethyleneoxy) ethanol, and polyoxamers.

In various embodiments, the polymeric composition may comprise a pharmaceutically active agent. The polymeric composition may release a therapeutically effective amount of the pharmaceutically active agent. In various embodiments, the pharmaceutically active agent may be released as the polymeric composition is desorbed/absorbed. In various embodiments, the pharmaceutically active agent may be released into fluid, such as, for example, blood, passing over or through the polymeric composition. Examples of pharmaceutically active agents may include, but are not limited to, haemostatic agents and drugs, such as, for example, fibrin, thrombin, and oxidized regenerated cellulose (ORC); anti-inflammatory drugs, such as, for example, diclofenac, aspirin, naproxen, sulindac, and hydrocortisone; antibiotic and antimicrobial drug or agents, such as, for example, triclosan, ionic silver, ampicillin, gentamicin, polymyxin B, chloramphenicol; and anticancer agents, such as, for example, cisplatin, mitomycin, adriamycin.

In various embodiments, the polymeric composition may comprise a haemostatic material. The tissue thickness compensator may comprise haemostatic materials comprising poly(lactic acid), poly(glycolic acid), poly(hydroxybutyrate), poly(caprolactone), poly(dioxanone), polyalkyleneoxides,

copoly(ether-esters), collagen, gelatin, thrombin, fibrin, fibrinogen, fibronectin, elastin, albumin, hemoglobin, ovalbumin, polysaccharides, hyaluronic acid, chondroitin sulfate, hydroxyethyl starch, hydroxyethyl cellulose, cellulose, oxidized cellulose, hydroxypropyl cellulose, carboxyethyl cellulose, carboxymethyl cellulose, chitan, chitosan, agarose, maltose, maltodextrin, alginate, clotting factors, methacrylate, polyurethanes, cyanoacrylates, platelet agonists, vasoconstrictors, alum, calcium, RGD peptides, proteins, protamine sulfate,  $\epsilon$ -amino caproic acid, ferric sulfate, ferric subsulfates, ferric chloride, zinc, zinc chloride, aluminum chloride, aluminum sulfates, aluminum acetates, permanganates, tannins, bone wax, polyethylene glycols, fucans and combinations thereof. The tissue thickness compensator may be characterized by haemostatic properties.

The polymeric composition of a tissue thickness compensator may be characterized by percent porosity, pore size, and/or hardness, for example. In various embodiments, the polymeric composition may have a percent porosity from approximately 30% by volume to approximately 99% by volume, for example. In certain embodiments, the polymeric composition may have a percent porosity from approximately 60% by volume to approximately 98% by volume, for example. In various embodiments, the polymeric composition may have a percent porosity from approximately 85% by volume to approximately 97% by volume, for example. In at least one embodiment, the polymeric composition may comprise approximately 70% by weight of PLLA and approximately 30% by weight of PCL, for example, and can comprise approximately 90% porosity by volume, for example. In at least one such embodiment, as a result, the polymeric composition would comprise approximately 10% copolymer by volume. In at least one embodiment, the polymeric composition may comprise approximately 65% by weight of PGA and approximately 35% by weight of PCL, for example, and can have a percent porosity from approximately 93% by volume to approximately 95% by volume, for example. In various embodiments, the polymeric composition may comprise greater than 85% porosity by volume. The polymeric composition may have a pore size from approximately 5 micrometers to approximately 2000 micrometers, for example. In various embodiments, the polymeric composition may have a pore size between approximately 10 micrometers to approximately 100 micrometers, for example. In at least one such embodiment, the polymeric composition can comprise a copolymer of PGA and PCL, for example. In certain embodiments, the polymeric composition may have a pore size between approximately 100 micrometers to approximately 1000 micrometers, for example. In at least one such embodiment, the polymeric composition can comprise a copolymer of PLLA and PCL, for example.

According to certain aspects, the hardness of a polymeric composition may be expressed in terms of the Shore Hardness, which can be defined as the resistance to permanent indentation of a material as determined with a durometer, such as a Shore Durometer. In order to assess the durometer value for a given material, a pressure is applied to the material with a durometer indenter foot in accordance with ASTM procedure D2240-00, entitled, "Standard Test Method for Rubber Property-Durometer Hardness", the entirety of which is incorporated herein by reference. The durometer indenter foot may be applied to the material for a sufficient period of time, such as 15 seconds, for example, wherein a reading is then taken from the appropriate scale. Depending on the type of scale being used, a reading of 0 can be obtained when the indenter foot completely penetrates the material, and a reading of 100 can be obtained when no penetration into the material occurs.

This reading is dimensionless. In various embodiments, the durometer may be determined in accordance with any suitable scale, such as Type A and/or Type OO scales, for example, in accordance with ASTM D2240-00. In various embodiments, the polymeric composition of a tissue thickness compensator may have a Shore A hardness value from approximately 4 A to approximately 16 A, for example, which is approximately 45 OO to approximately 65 OO on the Shore OO range. In at least one such embodiment, the polymeric composition can comprise a PLLA/PCL copolymer or a PGA/PCL copolymer, for example. In various embodiments, the polymeric composition of a tissue thickness compensator may have a Shore A Hardness value of less than 15 A. In various embodiments, the polymeric composition of a tissue thickness compensator may have a Shore A Hardness value of less than 10 A. In various embodiments, the polymeric composition of a tissue thickness compensator may have a Shore A Hardness value of less than 5 A. In certain embodiments, the polymeric material may have a Shore OO composition value from approximately 35 OO to approximately 75 OO, for example.

In various embodiments, the polymeric composition may have at least two of the above-identified properties. In various embodiments, the polymeric composition may have at least three of the above-identified properties. The polymeric composition may have a porosity from 85% to 97% by volume, a pore size from 5 micrometers to 2000 micrometers, and a Shore A hardness value from 4 A to 16 A and Shore OO hardness value from 45 OO to 65 OO, for example. In at least one embodiment, the polymeric composition may comprise 70% by weight of the polymeric composition of PLLA and 30% by weight of the polymeric composition of PCL having a porosity of 90% by volume, a pore size from 100 micrometers to 1000 micrometers, and a Shore A hardness value from 4 A to 16 A and Shore OO hardness value from 45 OO to 65 OO, for example. In at least one embodiment, the polymeric composition may comprise 65% by weight of the polymeric composition of PGA and 35% by weight of the polymeric composition of PCL having a porosity from 93% to 95% by volume, a pore size from 10 micrometers to 100 micrometers, and a Shore A hardness value from 4 A to 16 A and Shore OO hardness value from 45 OO to 65 OO, for example.

In various embodiments, the tissue thickness compensator may comprise a material that expands. As discussed above, the tissue thickness compensator may comprise a compressed material that expands when uncompressed or deployed, for example. In various embodiments, the tissue thickness compensator may comprise a self-expanding material formed in situ. In various embodiments, the tissue thickness compensator may comprise at least one precursor selected to spontaneously crosslink when contacted with at least one of other precursor(s), water, and/or bodily fluids. In various embodiments, a first precursor may contact one or more other precursors to form an expandable and/or swellable tissue thickness compensator. In various embodiments, the tissue thickness compensator may comprise a fluid-swellable composition, such as a water-swellable composition, for example. In various embodiments, the tissue thickness compensator may comprise a gel comprising water.

In various embodiments, the tissue thickness compensator may comprise a biodegradable foam having an encapsulation comprising dry hydrogel particles or granules embedded therein. Without wishing to be bound to any particular theory, the encapsulations in the foam may be formed by contacting an aqueous solution of a hydrogel precursor and an organic

solution may form micelles. The aqueous solution and organic solution may be dried to encapsulate dry hydrogel particles or granules within the foam. For example, a hydrogel precursor, such as a hydrophilic polymer, may be dissolved in water to form a dispersion of micelles. The aqueous solution may contact an organic solution of dioxane comprising poly(glycolic acid) and polycaprolactone. The aqueous and organic solutions may be lyophilized to form a biodegradable foam having dry hydrogel particles or granules dispersed therein. Without wishing to be bound to any particular theory, it is believed that the micelles form the encapsulation having the dry hydrogel particles or granules dispersed within the foam structure. In certain embodiments, the encapsulation may be ruptured, and the dry hydrogel particles or granules may contact a fluid, such as a bodily fluid, and expand.

In various embodiments, as described above, the tissue thickness compensator may comprise an initial thickness and an expanded thickness. In certain embodiments, the initial thickness of a tissue thickness compensator can be approximately 0.001% of its expanded thickness, approximately 0.01% of its expanded thickness, approximately 0.1% of its expanded thickness, approximately 1% of its expanded thickness, approximately 10% of its expanded thickness, approximately 20% of its expanded thickness, approximately 30% of its expanded thickness, approximately 40% of its expanded thickness, approximately 50% of its expanded thickness, approximately 60% of its expanded thickness, approximately 70% of its expanded thickness, approximately 80% of its expanded thickness, and/or approximately 90% of its expanded thickness, for example. In various embodiments, the expanded thickness of the tissue thickness compensator can be approximately two times, approximately five times, approximately ten times, approximately fifty times, approximately one hundred times, approximately two hundred times, approximately three hundred times, approximately four hundred times, approximately five hundred times, approximately six hundred times, approximately seven hundred times, approximately eight hundred times, approximately nine hundred times, and/or approximately one thousand times thicker than its initial thickness, for example. In various embodiments, the initial thickness of the tissue thickness compensator can be up to 1% its expanded thickness, up to 5% its expanded thickness, up to 10% its expanded thickness, and up to 50% its expanded thickness. In various embodiments, the expanded thickness of the tissue thickness compensator can be at least 50% thicker than its initial thickness, at least 100% thicker than its initial thickness, at least 300% thicker than its initial thickness, and at least 500% thicker than its initial thickness. As described above, in various circumstances, as a result of the above, the tissue thickness compensator can be configured to consume any gaps within the staple entrapment area.

As discussed above, in various embodiments, the tissue thickness compensator may comprise a hydrogel. In various embodiments, the hydrogel may comprise homopolymer hydrogels, copolymer hydrogels, multipolymer hydrogels, interpenetrating polymer hydrogels, and combinations thereof. In various embodiments, the hydrogel may comprise microgels, nanogels, and combinations thereof. The hydrogel may generally comprise a hydrophilic polymer network capable of absorbing and/or retaining fluids. In various embodiments, the hydrogel may comprise a non-crosslinked hydrogel, a crosslinked hydrogel, and combinations thereof. The hydrogel may comprise chemical crosslinks, physical crosslinks, hydrophobic segments and/or water insoluble segments. The hydrogel may be chemically crosslinked by polymerization, small-molecule crosslinking, and/or polymer-

polymer crosslinking. The hydrogel may be physically crosslinked by ionic interactions, hydrophobic interactions, hydrogen bonding interactions, stereocomplexation, and/or supramolecular chemistry. The hydrogel may be substantially insoluble due to the crosslinks, hydrophobic segments and/or water insoluble segments, but be expandable and/or swellable due to absorbing and/or retaining fluids. In certain embodiments, the precursor may crosslink with endogenous materials and/or tissues.

In various embodiments, the hydrogel may comprise an environmentally sensitive hydrogel (ESH). The ESH may comprise materials having fluid-swelling properties that relate to environmental conditions. The environmental conditions may include, but are not limited to, the physical conditions, biological conditions, and/or chemical conditions at the surgical site. In various embodiments, the hydrogel may swell or shrink in response to temperature, pH, electric fields, ionic strength, enzymatic and/or chemical reactions, electrical and/or magnetic stimuli, and other physiological and environmental variables, for example. In various embodiments, the ESH may comprise multifunctional acrylates, hydroxyethylmethacrylate (HEMA), elastomeric acrylates, and related monomers.

In various embodiments, the tissue thickness compensator comprising a hydrogel may comprise at least one of the non-synthetic materials and synthetic materials described above. The hydrogel may comprise a synthetic hydrogel and/or a non-synthetic hydrogel. In various embodiments, the tissue thickness compensator may comprise a plurality of layers. The plurality of the layers may comprise porous layers and/or non-porous layers. For example, the tissue thickness compensator may comprise a non-porous layer and a porous layer. In another example, the tissue thickness compensator may comprise a porous layer intermediate a first non-porous layer and a second non-porous layer. In another example, the tissue thickness compensator may comprise a non-porous layer intermediate a first porous layer and a second porous layer. The non-porous layers and porous layers may be positioned in any order relative to the surfaces of the staple cartridge and/or anvil.

Examples of the non-synthetic material may include, but are not limited to, albumin, alginate, carbohydrate, casein, cellulose, chitin, chitosan, collagen, blood, dextran, elastin, fibrin, fibrinogen, gelatin, heparin, hyaluronic acid, keratin, protein, serum, and starch. The cellulose may comprise hydroxyethyl cellulose, oxidized cellulose, oxidized regenerated cellulose (ORC), hydroxypropyl cellulose, carboxyethyl cellulose, carboxymethylcellulose, and combinations thereof. The collagen may comprise bovine pericardium. The carbohydrate may comprise a polysaccharide, such as lyophilized polysaccharide. The protein may comprise glycoprotein, proteoglycan, and combinations thereof.

Examples of the synthetic material may include, but are not limited to, poly(lactic acid), poly(glycolic acid), poly(hydroxybutyrate), poly(phosphazene), polyesters, polyethylene glycols, polyethylene oxide, polyethylene oxide-co-polypropylene oxide, co-polyethylene oxide, polyalkyleneoxides, polyacrylamides, polyhydroxyethylmethacrylate, poly(vinylpyrrolidone), polyvinyl alcohols, poly(caprolactone), poly(dioxanone), polyacrylic acid, polyacetate, polypropylene, aliphatic polyesters, glycerols, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), polyoxaesters, polyorthoesters, polyphosphazenes and combinations thereof. In certain embodiments, the above non-synthetic materials may be synthetically prepared, e.g., synthetic hyaluronic acid, utilizing conventional methods.

In various embodiments, the hydrogel may be made from one or more hydrogel precursors. The precursor may comprise a monomer and/or a macromer. The hydrogel precursor may comprise an electrophile functional group and/or a nucleophile electrophile functional group. In general, electrophiles may react with nucleophiles to form a bond. The term "functional group" as used herein refers to electrophilic or nucleophilic groups capable of reacting with each other to form a bond. Examples of electrophilic functional groups may include, but are not limited to, N-hydroxysuccinimides ("NHS"), sulfosuccinimides, carbonyldiimidazole, sulfonyl chloride, aryl halides, sulfosuccinimidyl esters, N-hydroxysuccinimidyl esters, succinimidyl esters such as succinimidyl succinates and/or succinimidyl propionates, isocyanates, thiocyanates, carbodiimides, benzotriazole carbonates, epoxides, aldehydes, maleimides, imidoesters, combinations thereof, and the like. In at least one embodiment, the electrophilic functional group may comprise a succinimidyl ester. Examples of nucleophile functional groups may include, but are not limited to,  $\text{—NH}_2$ ,  $\text{—SH}$ ,  $\text{—OH}$ ,  $\text{—PH}_2$ , and  $\text{—CO—NH—NH}_2$ .

In various embodiments, the hydrogel may be formed from a single precursor or multiple precursors. In certain embodiments, the hydrogel may be formed from a first precursor and a second precursor. The first hydrogel precursor and second hydrogel precursor may form a hydrogel in situ and/or in vivo upon contact. The hydrogel precursor may generally refer to a polymer, functional group, macromolecule, small molecule, and/or crosslinker that can take part in a reaction to form a hydrogel. The precursor may comprise a homogeneous solution, heterogeneous, or phase separated solution in a suitable solvent, such as water or a buffer, for example. The buffer may have a pH from about 8 to about 12, such as, about 8.2 to about 9, for example. Examples of buffers may include, but are not limited to borate buffers. In certain embodiments, the precursor(s) may be in an emulsion. In various embodiments, a first precursor may react with a second precursor to form a hydrogel. In various embodiments, the first precursor may spontaneously crosslink when contacted with the second precursor. In various embodiments, a first set of electrophilic functional groups on a first precursor may react with a second set of nucleophilic functional groups on a second precursor. When the precursors are mixed in an environment that permits reaction (e.g., as relating to pH, temperature, and/or solvent), the functional groups may react with each other to form covalent bonds. The precursors may become crosslinked when at least some of the precursors react with more than one other precursor.

In various embodiments, the tissue thickness compensator may comprise at least one monomer selected from the group consisting of 3-sulfopropyl acrylate potassium salt ("KSPA"), sodium acrylate ("NaA"), N-(tris(hydroxymethyl)methyl)acrylamide ("tris acryl"), and 2-acrylamido-2-methyl-1-propane sulfonic acid (AMPS). The tissue thickness compensator may comprise a copolymer comprising two or more monomers selected from the group consisting of KSPA, NaA, tris acryl, AMPS. The tissue thickness compensator may comprise homopolymers derived from KSPA, NaA, trisacryl and AMPS. The tissue thickness compensator may comprise hydrophilicity modifying monomers copolymerizable therewith. The hydrophilicity modifying monomers may comprise methylmethacrylate, butylacrylate, cyclohexylacrylate, styrene, styrene sulphonic acid.

In various embodiments, the tissue thickness compensator may comprise a crosslinker. The crosslinker may comprise a low molecular weight di- or polyvinyl crosslinking agent, such as ethylenglycol diacrylate or dimethacrylate, di-, tri- or

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tetraethylen-glycol diacrylate or dimethacrylate, allyl (meth) acrylate, a C<sub>2</sub>-C<sub>8</sub>-alkylene diacrylate or dimethacrylate, divinyl ether, divinyl sulfone, di- and trivinylbenzene, trimethylolpropane triacrylate or trimethacrylate, pentaerythritol tetraacrylate or tetramethacrylate, bisphenol A diacrylate or dimethacrylate, methylene bisacrylamide or bismethacrylamide, ethylene bisacrylamide or ethylene bismethacrylamide, triallyl phthalate or diallyl phthalate. In at least one embodiment, the crosslinker may comprise N,N'-methylenebisacrylamide ("MBAA").

In various embodiments, the tissue thickness compensator may comprise at least one of acrylate and/or methacrylate functional hydrogels, biocompatible photoinitiator, alkyl-cyanoacrylates, isocyanate functional macromers, optionally comprising amine functional macromers, succinimidyl ester functional macromers, optionally comprising amine and/or sulfhydryl functional macromers, epoxy functional macromers, optionally comprising amine functional macromers, mixtures of proteins and/or polypeptides and aldehyde crosslinkers, Genipin, and water-soluble carbodiimides, anionic polysaccharides and polyvalent cations.

In various embodiments, the tissue thickness compensator may comprise unsaturated organic acid monomers, acrylic substituted alcohols, and/or acrylamides. In various embodiments, the tissue thickness compensator may comprise methacrylic acids, acrylic acids, glycerolacrylate, glycerolmethacrylate, 2-hydroxyethylmethacrylate, 2-hydroxyethylacrylate, 2-(dimethylaminoethyl) methacrylate, N-vinyl pyrrolidone, methacrylamide, and/or N,N-dimethylacrylamide poly(methacrylic acid).

In various embodiments, the tissue thickness compensator may comprise a reinforcement material. In various embodiments, the reinforcement material may comprise at least one of the non-synthetic materials and synthetic materials described above. In various embodiments, the reinforcement material may comprise collagen, gelatin, fibrin, fibrinogen, elastin, keratin, albumin, hydroxyethyl cellulose, cellulose, oxidized cellulose, hydroxypropyl cellulose, carboxyethyl cellulose, carboxymethylcellulose, chitan, chitosan, alginate, poly(lactic acid), poly(glycolic acid), poly(hydroxybutyrate), poly(phosphazine), polyesters, polyethylene glycols, polyalkyleneoxides, polyacrylamides, polyhydroxyethylmethacrylate, polyvinylpyrrolidone, polyvinyl alcohols, poly( $\epsilon$ -caprolactone), poly(dioxanone), polyacrylic acid, polyacetate, polycaprolactone, polypropylene, aliphatic polyesters, glycerols, poly(amino acids), copoly(ether-esters), polyalkylene oxalates, polyamides, poly(iminocarbonates), polyalkylene oxalates, polyoxaesters, polyorthoesters, polyphosphazenes and combinations thereof.

In various embodiments, the tissue thickness compensator may comprise a layer comprising the reinforcement material. In certain embodiments, a porous layer and/or a non-porous layer of a tissue thickness compensator may comprise the reinforcement material. For example, the porous layer may comprise the reinforcement material and the non-porous layer may not comprise the reinforcement material. In various embodiments, the reinforcement layer may comprise an inner layer intermediate a first non-porous layer and a second non-porous layer. In certain embodiments, the reinforcement layer may comprise an outer layer of the tissue thickness compensator. In certain embodiments, the reinforcement layer may comprise an exterior surface of the tissue thickness compensator.

In various embodiments, the reinforcement material may comprise meshes, monofilaments, multifilament braids, fibers, mats, felts, particles, and/or powders. In certain embodiments, the reinforcement material may be incorpo-

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rated into a layer of the tissue thickness compensator. The reinforcement material may be incorporated into at least one of a non-porous layer and a porous layer. A mesh comprising the reinforcement material may be formed using conventional techniques, such as, for example, knitting, weaving, tatting, and/or knipling. In various embodiments, a plurality of reinforcement materials may be oriented in a random direction and/or a common direction. In certain embodiments, the common direction may be one of parallel to the staple line and perpendicular to the staple line, for example. For example, the monofilaments and/or multifilament braids may be oriented in a random direction and/or a common direction. The monofilaments and multifilament braids may be associated with the non-porous layer and/or the porous layer. In various embodiments, the tissue thickness compensator may comprise a plurality of reinforcement fibers oriented in a random direction within a non-porous layer. In various embodiments, the tissue thickness compensator may comprise a plurality of reinforcement fibers oriented in a common direction within a non-porous layer.

The fibers may form a non-woven material, such as, for example, a mat and a felt. The fibers may have any suitable length, such as, for example from 0.1 mm to 100 mm and 0.4 mm to 50 mm. The reinforcement material may be ground to a powder. The powder may have a particle size from 10 micrometers to 1 cm, for example. The powder may be incorporated into the tissue thickness compensator.

In various embodiments, the tissue thickness compensator may be formed in situ. In various embodiments, the hydrogel may be formed in situ. The tissue thickness compensator may be formed in situ by covalent, ionic, and/or hydrophobic bonds. Physical (non-covalent) crosslinks may result from complexation, hydrogen bonding, desolvation, Van der Waals interactions, ionic bonding, and combinations thereof. Chemical (covalent) crosslinking may be accomplished by any of a number of mechanisms, including: free radical polymerization, condensation polymerization, anionic or cationic polymerization, step growth polymerization, electrophile-nucleophile reactions, and combinations thereof.

In various embodiments, in situ formation of the tissue thickness compensator may comprise reacting two or more precursors that are physically separated until contacted in situ and/or react to an environmental condition to react with each other to form the hydrogel. In situ polymerizable polymers may be prepared from precursor(s) that can be reacted to form a polymer at the surgical site. The tissue thickness compensator may be formed by crosslinking reactions of the precursor(s) in situ. In certain embodiments, the precursor may comprise an initiator capable of initiating a polymerization reaction for the formation of the in situ tissue thickness compensator. The tissue thickness compensator may comprise a precursor that can be activated at the time of application to create, in various embodiments, a crosslinked hydrogel. In situ formation of the tissue thickness compensator may comprise activating at least one precursor to form bonds to form the tissue thickness compensator. In various embodiments, activation may be achieved by changes in the physical conditions, biological conditions, and/or chemical conditions at the surgical site, including, but not limited to temperature, pH, electric fields, ionic strength, enzymatic and/or chemical reactions, electrical and/or magnetic stimuli, and other physiological and environmental variables. In various embodiments, the precursors may be contacted outside the body and introduced to the surgical site.

In various embodiments, the tissue thickness compensator may comprise one or more encapsulations, or cells, which can be configured to store at least one component therein. In

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certain embodiments, the encapsulation may be configured to store a hydrogel precursor therein. In certain embodiments, the encapsulation may be configured to store two components therein, for example. In certain embodiments, the encapsulation may be configured to store a first hydrogel precursor and a second hydrogel precursor therein. In certain embodiments, a first encapsulation may be configured to store a first hydrogel precursor therein and a second encapsulation may be configured to store a second hydrogel precursor therein. As described above, the encapsulations can be aligned, or at least substantially aligned, with the staple legs to puncture and/or otherwise rupture the encapsulations when the staple legs contact the encapsulation. In certain embodiments, the encapsulations may be compressed, crushed, collapsed, and/or otherwise ruptured when the staples are deployed. After the encapsulations have been ruptured, the component(s) stored therein can flow out of the encapsulation. The component stored therein may contact other components, layers of the tissue thickness compensator, and/or the tissue. In various embodiments, the other components may be flowing from the same or different encapsulations, provided in the layers of the tissue thickness compensator, and/or provided to the surgical site by the clinician. As a result of the above, the component(s) stored within the encapsulations can provide expansion and/or swelling of the tissue thickness compensator.

In various embodiments, the tissue thickness compensator may comprise a layer comprising the encapsulations. In various embodiments, the encapsulation may comprise a void, a pocket, a dome, a tube, and combinations thereof associated with the layer. In certain embodiments, the encapsulations may comprise voids in the layer. In at least one embodiment, the layer can comprise two layers that can be attached to one another wherein the encapsulations can be defined between the two layers. In certain embodiments, the encapsulations may comprise domes on the surface of the layer. For example, at least a portion of the encapsulations can be positioned within domes extending upwardly from the layer. In certain embodiments, the encapsulations may comprise pockets formed within the layer. In certain embodiments, a first portion of the encapsulations may comprise a dome and a second portion of the encapsulations may comprise a pocket. In certain embodiments, the encapsulations may comprise a tube embedded within the layer. In certain embodiments, the tube may comprise the non-synthetic materials and/or synthetic materials described herein, such as PLA. In at least one embodiment, the tissue thickness compensator may comprise a bioabsorbable foam, such as ORC, comprising PLA tubes embedded therein, and the tube may encapsulate a hydrogel, for example. In certain embodiments, the encapsulations may comprise discrete cells that are unconnected to each other. In certain embodiments, one or more of the encapsulations can be in fluid communication with each other via one or more passageways, conduits, and/or channels, for example, extending through the layer.

The rate of release of a component from the encapsulation may be controlled by the thickness of the tissue thickness compensator, the composition of tissue thickness compensator, the size of the component, the hydrophilicity of the component, and/or the physical and/or chemical interactions among the component, the composition of the tissue thickness compensator, and/or the surgical instrument, for example. In various embodiments, the layer can comprise one or more thin sections or weakened portions, such as partial perforations, for example, which can facilitate the incision of the layer and the rupture of the encapsulations. In various embodiments, the partial perforations may not completely

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extend through a layer while, in certain embodiments, perforations may completely extend through the layer.

In various embodiments, an anvil may comprise a tissue thickness compensator comprising an encapsulated component comprising at least one microsphere particle. In certain embodiments, the tissue thickness compensator may comprise an encapsulation comprising a first encapsulated component and a second encapsulated component. In certain embodiments, the tissue thickness compensator may comprise an encapsulation comprising a first microsphere particle and a second microsphere particle.

In various embodiments, the tissue thickness compensator may be suitable for use with a surgical instrument. As described above the tissue thickness compensator may be associated with the staple cartridge and/or the anvil. The tissue thickness compensator may be configured into any shape, size and/or dimension suitable to fit the staple cartridge and/or anvil. As described herein, the tissue thickness compensator may be releasably attached to the staple cartridge and/or anvil. The tissue thickness compensator may be attached to the staple cartridge and/or anvil in any mechanical and/or chemical manner capable of retaining the tissue thickness compensator in contact with the staple cartridge and/or anvil prior to and during the stapling process. The tissue thickness compensator may be removed or released from the staple cartridge and/or anvil after the staple penetrates the tissue thickness compensator. The tissue thickness compensator may be removed or released from the staple cartridge and/or anvil as the staple cartridge and/or anvil is moved away from the tissue thickness compensator.

In various embodiments, referring now to FIG. 14, a staple cartridge, such as staple cartridge 10000, for example, can comprise a support portion 10010 and a compressible tissue thickness compensator 10020. Referring now to FIGS. 16-18, the support portion 10010 can comprise a deck surface 10011 and a plurality of staple cavities 10012 defined within the support portion 10010. Each staple cavity 10012 can be sized and configured to removably store a staple, such as a staple 10030, for example, therein. The staple cartridge 10000 can further comprise a plurality of staple drivers 10040 which can each be configured to support one or more staples 10030 within the staple cavities 10012 when the staples 10030 and the staple drivers 10040 are in their unfired positions. In at least one such embodiment, referring primarily to FIGS. 22 and 23, each staple driver 10040 can comprise one or more cradles, or troughs, 10041, for example, which can be configured to support the staples and limit relative movement between the staples 10030 and the staple drivers 10040. In various embodiments, referring again to FIG. 16, the staple cartridge 10000 can further comprise a staple-firing sled 10050 which can be moved from a proximal end 10001 to a distal end 10002 of the staple cartridge in order to sequentially lift the staple drivers 10040 and the staples 10030 from their unfired positions toward an anvil positioned opposite the staple cartridge 10000. In certain embodiments, referring primarily to FIGS. 16 and 18, each staple 10030 can comprise a base 10031 and one or more legs 10032 extending from the base 10031 wherein each staple can be at least one of substantially U-shaped and substantially V-shaped, for example. In at least one embodiment, the staples 10030 can be configured such that the tips of the staple legs 10032 are recessed with respect to the deck surface 10011 of the support portion 10010 when the staples 10030 are in their unfired positions. In at least one embodiment, the staples 10030 can be configured such that the tips of the staple legs 10032 are flush with respect to the deck surface 10011 of the support portion 10010 when the staples 10030 are in their unfired positions. In

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at least one embodiment, the staples **10030** can be configured such that the tips of the staple legs **10032**, or at least some portion of the staple legs **10032**, extend above the deck surface **10011** of the support portion **10010** when the staples **10030** are in their unfired positions. In such embodiments, the staple legs **10032** can extend into and can be embedded within the tissue thickness compensator **10020** when the staples **10030** are in their unfired positions. In at least one such embodiment, the staple legs **10032** can extend above the deck surface **10011** by approximately 0.075", for example. In various embodiments, the staple legs **10032** can extend above the deck surface **10011** by a distance between approximately 0.025" and approximately 0.125", for example. In certain embodiments, further to the above, the tissue thickness compensator **10020** can comprise an uncompressed thickness between approximately 0.08" and approximately 0.125", for example.

In use, further to the above and referring primarily to FIG. 31, an anvil, such as anvil, **10060**, for example, can be moved into a closed position opposite the staple cartridge **10000**. As described in greater detail below, the anvil **10060** can position tissue against the tissue thickness compensator **10020** and, in various embodiments, compress the tissue thickness compensator **10020** against the deck surface **10011** of the support portion **10010**, for example. Once the anvil **10060** has been suitably positioned, the staples **10030** can be deployed, as also illustrated in FIG. 31. In various embodiments, as mentioned above, the staple-firing sled **10050** can be moved from the proximal end **10001** of the staple cartridge **10000** toward the distal end **10002**, as illustrated in FIG. 32. As the sled **10050** is advanced, the sled **10050** can contact the staple drivers **10040** and lift the staple drivers **10040** upwardly within the staple cavities **10012**. In at least one embodiment, the sled **10050** and the staple drivers **10040** can each comprise one or more ramps, or inclined surfaces, which can co-operate to move the staple drivers **10040** upwardly from their unfired positions. In at least one such embodiment, referring to FIGS. 19-23, each staple driver **10040** can comprise at least one inclined surface **10042** and the sled **10050** can comprise one or more inclined surfaces **10052** which can be configured such that the inclined surfaces **10052** can slide under the inclined surface **10042** as the sled **10050** is advanced distally within the staple cartridge. As the staple drivers **10040** are lifted upwardly within their respective staple cavities **10012**, the staple drivers **10040** can lift the staples **10030** upwardly such that the staples **10030** can emerge from their staple cavities **10012** through openings in the staple deck **10011**. During an exemplary firing sequence, referring primarily to FIGS. 25-27, the sled **10050** can first contact staple **10030a** and begin to lift the staple **10030a** upwardly. As the sled **10050** is advanced further distally, the sled **10050** can begin to lift staples **10030b**, **10030c**, **10030d**, **10030e**, and **10030f**, and any other subsequent staples, in a sequential order. As illustrated in FIG. 27, the sled **10050** can drive the staples **10030** upwardly such that the legs **10032** of the staples contact the opposing anvil, are deformed to a desired shape, and ejected therefrom the support portion **10010**. In various circumstances, the sled **10030** can move several staples upwardly at the same time as part of a firing sequence. With regard to the firing sequence illustrated in FIG. 27, the staples **10030a** and **10030b** have been moved into their fully fired positions and ejected from the support portion **10010**, the staples **10030c** and **10030d** are in the process of being fired and are at least partially contained within the support portion **10010**, and the staples **10030e** and **10030f** are still in their unfired positions.

As discussed above, and referring to FIG. 33, the staple legs **10032** of the staples **10030** can extend above the deck

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surface **10011** of the support portion **10010** when the staples **10030** are in their unfired positions. With further regard to this firing sequence illustrated in FIG. 27, the staples **10030e** and **10030f** are illustrated in their unfired position and their staple legs **10032** extend above the deck surface **10011** and into the tissue thickness compensator **10020**. In various embodiments, the tips of the staple legs **10032**, or any other portion of the staple legs **10032**, may not protrude through a top tissue-contacting surface **10021** of the tissue thickness compensator **10020** when the staples **10030** are in their unfired positions. As the staples **10030** are moved from their unfired positions to their fired positions, as illustrated in FIG. 27, the tips of the staple legs can protrude through the tissue-contacting surface **10032**. In various embodiments, the tips of the staple legs **10032** can comprise sharp tips which can incise and penetrate the tissue thickness compensator **10020**. In certain embodiments, the tissue thickness compensator **10020** can comprise a plurality of apertures which can be configured to receive the staple legs **10032** and allow the staple legs **10032** to slide relative to the tissue thickness compensator **10020**. In certain embodiments, the support portion **10010** can further comprise a plurality of guides **10013** extending from the deck surface **10011**. The guides **10013** can be positioned adjacent to the staple cavity openings in the deck surface **10011** such that the staple legs **10032** can be at least partially supported by the guides **10013**. In certain embodiments, a guide **10013** can be positioned at a proximal end and/or a distal end of a staple cavity opening. In various embodiments, a first guide **10013** can be positioned at a first end of each staple cavity opening and a second guide **10013** can be positioned at a second end of each staple cavity opening such that each first guide **10013** can support a first staple leg **10032** of a staple **10030** and each second guide **10013** can support a second staple leg **10032** of the staple. In at least one embodiment, referring to FIG. 33, each guide **10013** can comprise a groove or slot, such as groove **10016**, for example, within which a staple leg **10032** can be slidably received. In various embodiments, each guide **10013** can comprise a cleat, protrusion, and/or spike that can extend from the deck surface **10011** and can extend into the tissue thickness compensator **10020**. In at least one embodiment, as discussed in greater detail below, the cleats, protrusions, and/or spikes can reduce relative movement between the tissue thickness compensator **10020** and the support portion **10010**. In certain embodiments, the tips of the staple legs **10032** may be positioned within the guides **10013** and may not extend above the top surfaces of the guides **10013** when the staples **10030** are in their unfired position. In at least such embodiment, the guides **10013** can define a guide height and the staples **10030** may not extend above this guide height when they are in their unfired position.

In various embodiments, a tissue thickness compensator, such as tissue thickness compensator **10020**, for example, can be comprised of a single sheet of material. In at least one embodiment, a tissue thickness compensator can comprise a continuous sheet of material which can cover the entire top deck surface **10011** of the support portion **10010** or, alternatively, cover less than the entire deck surface **10011**. In certain embodiments, the sheet of material can cover the staple cavity openings in the support portion **10010** while, in other embodiments, the sheet of material can comprise openings which can be aligned, or at least partially aligned, with the staple cavity openings. In various embodiments, a tissue thickness compensator can be comprised of multiple layers of material. In some embodiments, referring now to FIG. 15, a tissue thickness compensator can comprise a compressible core and a wrap surrounding the compressible core. In certain embodiments, a wrap **10022** can be configured to releasably hold the



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compressible core to the support portion 10010. In at least one such embodiment, the support portion 10010 can comprise one or more projections, such as projections 10014 (FIG. 18), for example, extending therefrom which can be received within one or more apertures and/or slots, such as apertures 10024, for example, defined in the wrap 10022. The projections 10014 and the apertures 10024 can be configured such that the projections 10014 can retain the wrap 10022 to the support portion 10010. In at least one embodiment, the ends of the projections 10014 can be deformed, such as by a heat-stake process, for example, in order to enlarge the ends of the projections 10014 and, as a result, limit the relative movement between the wrap 10022 and the support portion 10010. In at least one embodiment, the wrap 10022 can comprise one or more perforations 10025 which can facilitate the release of the wrap 10022 from the support portion 10010, as illustrated in FIG. 15. Referring now to FIG. 24, a tissue thickness compensator can comprise a wrap 10222 including a plurality of apertures 10223, wherein the apertures 10223 can be aligned, or at least partially aligned, with the staple cavity openings in the support portion 10010. In certain embodiments, the core of the tissue thickness compensator can also comprise apertures which are aligned, or at least partially aligned, with the apertures 10223 in the wrap 10222. In other embodiments, the core of the tissue thickness compensator can comprise a continuous body and can extend underneath the apertures 10223 such that the continuous body covers the staple cavity openings in the deck surface 10011.

In various embodiments, as described above, a tissue thickness compensator can comprise a wrap for releasably holding a compressible core to the support portion 10010. In at least one such embodiment, referring to FIG. 16, a staple cartridge can further comprise retainer clips 10026 which can be configured to inhibit the wrap, and the compressible core, from prematurely detaching from the support portion 10010. In various embodiments, each retainer clip 10026 can comprise apertures 10028 which can be configured to receive the projections 10014 extending from the support portion 10010 such that the retainer clips 10026 can be retained to the support portion 10010. In certain embodiments, the retainer clips 10026 can each comprise at least one pan portion 10027 which can extend underneath the support portion 10010 and can support and retain the staple drivers 10040 within the support portion 10010. In certain embodiments, as described above, a tissue thickness compensator can be removably attached to the support portion 10010 by the staples 10030. More particularly, as also described above, the legs of the staples 10030 can extend into the tissue thickness compensator 10020 when the staples 10030 are in their unfired position and, as a result, releasably hold the tissue thickness compensator 10020 to the support portion 10010. In at least one embodiment, the legs of the staples 10030 can be in contact with the sidewalls of their respective staple cavities 10012 wherein, owing to friction between the staple legs 10032 and the sidewalls, the staples 10030 and the tissue thickness compensator 10020 can be retained in position until the staples 10030 are deployed from the staple cartridge 10000. When the staples 10030 are deployed, the tissue thickness compensator 10020 can be captured within the staples 10030 and held against the stapled tissue T. When the anvil is thereafter moved into an open position to release the tissue T, the support portion 10010 can be moved away from the tissue thickness compensator 10020 which has been fastened to the tissue. In certain embodiments, an adhesive can be utilized to removably hold the tissue thickness compensator 10020 to the support portion 10010. In at least one embodiment, a two-part adhesive can be utilized wherein, in at least one

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embodiment, a first part of the adhesive can be placed on the deck surface 10011 and a second part of the adhesive can be placed on the tissue thickness compensator 10020 such that, when the tissue thickness compensator 10020 is placed against the deck surface 10011, the first part can contact the second part to active the adhesive and detachably bond the tissue thickness compensator 10020 to the support portion 10010. In various embodiments, any other suitable means could be used to detachably retain the tissue thickness compensator to the support portion of a staple cartridge.

In various embodiments, further to the above, the sled 10050 can be advanced from the proximal end 10001 to the distal end 10002 to fully deploy all of the staples 10030 contained within the staple cartridge 10000. In at least one embodiment, referring now to FIGS. 56-60, the sled 10050 can be advanced distally within a longitudinal cavity 10016 within the support portion 10010 by a firing member, or knife bar, 10052 of a surgical stapler. In use, the staple cartridge 10000 can be inserted into a staple cartridge channel in a jaw of the surgical stapler, such as staple cartridge channel 10070, for example, and the firing member 10052 can be advanced into contact with the sled 10050, as illustrated in FIG. 56. As the sled 10050 is advanced distally by the firing member 10052, the sled 10050 can contact the proximal-most staple driver, or drivers, 10040 and fire, or eject, the staples 10030 from the cartridge body 10010, as described above. As illustrated in FIG. 56, the firing member 10052 can further comprise a cutting edge 10053 which can be advanced distally through a knife slot in the support portion 10010 as the staples 10030 are being fired. In various embodiments, a corresponding knife slot can extend through the anvil positioned opposite the staple cartridge 10000 such that, in at least one embodiment, the cutting edge 10053 can extend between the anvil and the support portion 10010 and incise the tissue and the tissue thickness compensator positioned therebetween. In various circumstances, the sled 10050 can be advanced distally by the firing member 10052 until the sled 10050 reaches the distal end 10002 of the staple cartridge 10000, as illustrated in FIG. 58. At such point, the firing member 10052 can be retracted proximally. In some embodiments, the sled 10050 can be retracted proximally with the firing member 10052 but, in various embodiments, referring now to FIG. 59, the sled 10050 can be left behind in the distal end 10002 of the staple cartridge 10000 when the firing member 10052 is retracted. Once the firing member 10052 has been sufficiently retracted, the anvil can be re-opened, the tissue thickness compensator 10020 can be detached from the support portion 10010, and the remaining non-implanted portion of the expended staple cartridge 10000, including the support portion 10010, can be removed from the staple cartridge channel 10070.

After the expended staple cartridge 10000 has been removed from the staple cartridge channel, further to the above, a new staple cartridge 10000, or any other suitable staple cartridge, can be inserted into the staple cartridge channel 10070. In various embodiments, further to the above, the staple cartridge channel 10070, the firing member 10052, and/or the staple cartridge 10000 can comprise co-operating features which can prevent the firing member 10052 from being advanced distally a second, or subsequent, time without a new, or unfired, staple cartridge 10000 positioned in the staple cartridge channel 10070. More particularly, referring again to FIG. 56, as the firing member 10052 is advanced into contact with the sled 10050 and, when the sled 10050 is in its proximal unfired position, a support nose 10055 of the firing member 10052 can be positioned on and/or over a support ledge 10056 on the sled 10050 such that the firing member



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**10052** is held in a sufficient upward position to prevent a lock, or beam, **10054** extending from the firing member **10052** from dropping into a lock recess defined within the staple cartridge channel. As the lock **10054** will not drop into the lock recess, in such circumstances, the lock **10054** may not abut a distal sidewall **10057** of the lock recess as the firing member **10052** is advanced. As the firing member **10052** pushes the sled **10050** distally, the firing member **10052** can be supported in its upward firing position owing to the support nose **10055** resting on the support ledge **10056**. When the firing member **10052** is retracted relative to the sled **10050**, as discussed above and illustrated in FIG. 59, the firing member **10052** can drop downwardly from its upward position as the support nose **10055** is no longer resting on the support ledge **10056** of the sled **10050**. In at least one such embodiment, the surgical staple can comprise a spring **10058**, and/or any other suitable biasing element, which can be configured to bias the firing member **10052** into its downward position. Once the firing member **10052** has been completely retracted, as illustrated in FIG. 60, the firing member **10052** cannot be advanced distally through the spent staple cartridge **10000** once again. More particularly, the firing member **10052** can't be held in its upper position by the sled **10050** as the sled **10050**, at this point in the operating sequence, has been left behind at the distal end **10002** of the staple cartridge **10000**. Thus, as mentioned above, in the event that the firing member **10052** is advanced once again without replacing the staple cartridge, the lock beam **10054** will contact the sidewall **10057** of the lock recess which will prevent the firing member **10052** from being advanced distally into the staple cartridge **10000** once again. Stated another way, once the spent staple cartridge **10000** has been replaced with a new staple cartridge, the new staple cartridge will have a proximally-positioned sled **10050** which can hold the firing member **10052** in its upper position and allow the firing member **10052** to be advanced distally once again.

As described above, the sled **10050** can be configured to move the staple drivers **10040** between a first, unfired position and a second, fired position in order to eject staples **10030** from the support portion **10010**. In various embodiments, the staple drivers **10040** can be contained within the staple cavities **10012** after the staples **10030** have been ejected from the support portion **10010**. In certain embodiments, the support portion **10010** can comprise one or more retention features which can be configured to block the staple drivers **10040** from being ejected from, or falling out of, the staple cavities **10012**. In various other embodiments, the sled **10050** can be configured to eject the staple drivers **10040** from the support portion **10010** with the staples **10030**. In at least one such embodiment, the staple drivers **10040** can be comprised of a bioabsorbable and/or biocompatible material, such as Ultem, for example. In certain embodiments, the staple drivers can be attached to the staples **10030**. In at least one such embodiment, a staple driver can be molded over and/or around the base of each staple **10030** such that the driver is integrally formed with the staple. U.S. patent application Ser. No. 11/541,123, entitled SURGICAL STAPLES HAVING COMPRESSIBLE OR CRUSHABLE MEMBERS FOR SECURING TISSUE THEREIN AND STAPLING INSTRUMENTS FOR DEPLOYING THE SAME, filed on Sep. 29, 2006, is hereby incorporated by reference in its entirety.

As described above, a surgical stapling instrument can comprise a staple cartridge channel configured to receive a staple cartridge, an anvil rotatably coupled to the staple cartridge channel, and a firing member comprising a knife edge which is movable relative to the anvil and the staple cartridge

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channel. In use, a staple cartridge can be positioned within the staple cartridge channel and, after the staple cartridge has been at least partially expended, the staple cartridge can be removed from the staple cartridge channel and replaced with a new staple cartridge. In some such embodiments, the staple cartridge channel, the anvil, and/or the firing member of the surgical stapling instrument may be re-used with the replacement staple cartridge. In certain other embodiments, a staple cartridge may comprise a part of a disposable loading unit assembly which can include a staple cartridge channel, an anvil, and/or a firing member, for example, which can be replaced along with the staple cartridge as part of replacing the disposable loading unit assembly. Certain disposable loading unit assemblies are disclosed in U.S. patent application Ser. No. 12/031,817, entitled END EFFECTOR COUPLING ARRANGEMENTS FOR A SURGICAL CUTTING AND STAPLING INSTRUMENT, which was filed on Feb. 15, 2008, now U.S. Patent Application Publication No. 2009-0206131, the entire disclosure of which is incorporated by reference herein.

In various embodiments, the tissue thickness compensator may comprise an extrudable, a castable, and/or moldable composition comprising at least one of the synthetic and/or non-synthetic materials described herein. In various embodiments, the tissue thickness compensator may comprise a film or sheet comprising two or more layers. The tissue thickness compensator may be obtained using conventional methods, such as, for example, mixing, blending, compounding, spraying, wicking, solvent evaporating, dipping, brushing, vapor deposition, extruding, calendaring, casting, molding and the like. In extrusion, an opening may be in the form of a die comprising at least one opening to impart a shape to the emerging extrudate. In calendaring, an opening may comprise a nip between two rolls. Conventional molding methods may include, but are not limited to, blow molding, injection molding, foam injection, compression molding, thermoforming, extrusion, foam extrusion, film blowing, calendaring, spinning, solvent welding, coating methods, such as dip coating and spin coating, solution casting and film casting, plastisol processing (including knife coating, roller coating and casting), and combinations thereof. In injection molding, an opening may comprise a nozzle and/or channels/runners and/or mold cavities and features. In compression molding, the composition may be positioned in a mold cavity, heated to a suitable temperature, and shaped by exposure to compression under relatively high pressure. In casting, the composition may comprise a liquid or slurry that may be poured or otherwise provided into, onto and/or around a mold or object to replicate features of the mold or object. After casting, the composition may be dried, cooled, and/or cured to form a solid.

In various embodiments, a method of manufacturing a tissue thickness compensator comprising at least one medicament stored and/or absorbed therein may generally comprise providing a tissue thickness compensator and contacting the tissue thickness compensator and the medicament to retain the medicament in the tissue thickness compensator. In at least one embodiment, a method of manufacturing a tissue thickness compensator comprising an antibacterial material may comprise providing a hydrogel, drying the hydrogel, swelling the hydrogel in an aqueous solution of silver nitrate, contacting the hydrogel and a solution of sodium chloride to form the tissue thickness compensator having antibacterial properties. The tissue thickness compensator may comprise silver dispersed therein.

In various embodiments, referring now to FIG. 116, a tissue thickness compensator, such as tissue thickness com-

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compensator **22020**, for example, can be attached to an anvil of a surgical stapling instrument, such as anvil **22060**, for example. The tissue thickness compensator **22020** can include, in at least one embodiment, a cavity **22024** defined between a first film **22026** and a second film **22027**, wherein at least portions of the first film **22026** are attached to the second film **22027**. In at least one such embodiment, the first film **22026** can be attached to the second film **22027** along lateral seams **22028a** and **22028b**, for example. In various embodiments, the first film **22026** can be attached to the second film **22027** along a sealed perimeter in order to sealingly enclose the cavity **22024**. In certain embodiments, the first film **22026** and the second film **22027** can be thermally welded along the lateral seams **22028a**, **22028b** and/or any other seams connecting the films **22026** and **22027**, for example. Referring again to FIG. **116**, the anvil **22060** can comprise a plurality of staple forming pockets **22062** which can each be configured to receive and deform the leg of staple wherein, in at least one embodiment, the second film **22027** can comprise projections **22022** which can extend into the forming pockets **22062**. In certain embodiments, the projections **22022** can be sized and configured such that they fit snugly within the forming pockets **22062** and can retain the tissue thickness compensator **22020** to the anvil **22060**. In the illustrated embodiment, the anvil **22060** can comprise six rows of forming pockets **22062** wherein the tissue thickness compensator **22020** can similarly comprise six rows of projections **22022** which are aligned with the forming pockets **22062**, for example. Other embodiments comprising more than or less than six rows of forming pockets **22062** and/or projections **22022** could be utilized. In certain embodiments, one or more adhesives could be utilized to retain the tissue thickness compensator **22020** to the anvil **22060**.

As discussed above, the tissue thickness compensator **22020** can comprise a cavity **22024** defined therein. In various embodiments, the cavity **22024** can extend longitudinally along the anvil **22060**. Referring again to FIG. **116**, the tissue thickness compensator **22020** can comprise a compressible material positioned within the cavity **22024**. In at least one embodiment, referring now to FIG. **117**, staples, such as staples **22030**, for example, can be ejected from a staple cartridge such that the staples **22030** penetrate the tissue **T** and then penetrate the tissue thickness compensator **22020** before contacting the anvil **22060**. As the legs of the staples **22030** are deformed by the anvil **22060**, in various embodiments, the legs can be turned downwardly to repenetrate the tissue thickness compensator **22020** once again. In any event, once the staples **22030** have penetrated the tissue thickness compensator **22020**, one or more fluids contained in the cavity **22024**, for example, can flow or weep out of the tissue thickness compensator **22020** and onto the tissue **T**. In certain embodiments, the cavity **22024** can comprise one or more powders contained therein which can escape the cavity **22024** once the tissue thickness compensator **22020** has been at least partially ruptured by the staples **22030**, for example. In various embodiments, a material **22025** positioned within the cavity **22024** can be compressed or squeezed within the staples **22030** when the staples **22030** are deformed into their fired configurations such that, in at least one embodiment, a fluid stored within the material **22025** can be expressed from the material **22025**, for example. In various embodiments, referring again to FIG. **117**, the staples **22030** can also be configured to capture a tissue thickness compensator, such as compensator **22029**, for example, removably attached to the staple cartridge against the other side of the tissue **T**.

In various embodiments, further to the above, the material **22025** can comprise freeze-dried thrombin, freeze-dried

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fibrin, and/or small fiber non-woven oxidized regenerated cellulose, for example. In certain embodiments, the material **22025** can comprise a compressed powder wafer. In at least one embodiment, the sealed cavity **22024** can comprise an internal atmosphere having a pressure below that of the atmosphere surrounding the tissue thickness compensator **22020**. In such an embodiment, the pressure difference between the atmosphere in the internal cavity **22024** and the atmosphere can cause the films **22027** and **22028** to be drawn inwardly. When the internal cavity **22024** is ruptured by the staples **22030**, as described above, the vacuum within the internal cavity **22024** can equalize with the surrounding atmosphere and the material **22025** can escape the internal cavity **22024**, as also described above. In such circumstances, the tissue thickness compensator **22020** can expand and apply a compressive force to the tissue **T** captured within the staples **22030**. In embodiments in which the material **22025** is vacuum-packed within the tissue thickness compensator **22020**, the material **22025** can expand after the internal cavity **22024** has been punctured. In certain embodiments, the films **22026**, **22027** can be comprised of a bioabsorbable material and can be configured to dissolve once placed in the patient. In at least one such embodiment, each film **22026**, **22027** can be comprised of a layer, or laminate, which is between approximately 0.25 mils and approximately 0.50 mils thick, for example. In any event, further to the above, the tissue thickness compensator **22020**, including the material **22025**, can be transected by a cutting element as the staples **22030** are fired from their staple cartridge.

In certain embodiments, referring again to FIG. **116**, the cavity **22024** and the material **22025** of the tissue thickness compensator **22020** can be positioned underneath the inner four rows of staple forming pockets **22062** while the seams **22028a**, **22028b** can be positioned underneath the outer rows of forming pockets **22062**. In such embodiments, the staples in the outer rows of staples may not engage the material **22025** and, thus, they may not capture the material **22025** therein. Rather, such staples may only capture the films **22026** and **22027** along seams **22028a**, **22028b**. In various alternative embodiments, referring now to FIGS. **118** and **119**, a tissue thickness compensator **22120** can comprise, similar to the above, a first film **22126**, a second film **22127**, and a plurality of materials **22125a-d** captured between the first film **22126** and the second film **22127**. In at least one such embodiment, referring primarily to FIG. **118**, the first material **22125a** can be aligned with an outer row of staples **22030** in staple cartridge **22000** and an outer row of staple cavities **22062** in anvil **22060**, the second material **22125b** and the third material **22125c** can each be aligned with two inner rows of staples **22030** and staple cavities **22062**, and the fourth material **22125d** can be aligned with another outer row of staples **22030** and staple cavities **22062**. In such an embodiment, referring now to FIG. **119**, all of the staples **22030** can be arranged such that they can capture at least one of the materials **22125a-22125d** therein. As illustrated in FIGS. **118** and **119**, further to the above, the staples **22030** can be lifted upwardly between an unfired position and a fired position by staple drivers **22040** positioned within the staple cartridge **22000**.

In various embodiments, referring again to FIGS. **118** and **119**, the layers **22126** and **22127** can define one or more sealed cavities in which the materials **22125a-d** can be positioned. In at least one embodiment, the layers **22126** and **22127** can be sealed together along a perimeter which can include lateral seams **22128a** and **22128b**, for example, utilizing any suitable process, such as thermal and/or laser welding, for example. In certain embodiments, each of the mate-

rials **22125a-22125d** can be sealed within separate cavities while, in other embodiments, two or more of the materials **22125a-22125d** can be sealed within the same cavity. In various embodiments, the materials **22125a-22125d** can be comprised of the same material or materials while, in other embodiments, one or more of the materials **22125a-22125d** can be comprised of different materials. In at least one embodiment, one or more of the materials **22125a-22125d** can be comprised of sodium stearate and/or LAE, for example. In certain embodiments, the materials **22125a-22125d** can comprise a lubricant. In such embodiments, the legs of the staples **22030** can be exposed to the lubricant when the staple legs penetrate the materials **22125a-22125d** of the tissue thickness compensator **22120**. After the legs pass through the tissue thickness compensator **22120**, the legs can contact the anvil **22060** wherein the lubricant can reduce the coefficient of friction, and the friction forces, between the staple legs and the anvil **22060**. In such circumstances, the force needed to fire the staples **22030** can be reduced. Owing to the position of the tissue thickness compensator **22120** against the anvil **22060**, in at least one embodiment, the staple legs of the staples **22030** can contact the anvil **22060** directly after exiting the tissue thickness compensator **22120** thereby reducing the possibility that the lubricant may be wiped off the staple legs before they contact the anvil **22060**. Similarly, the staple legs of the staples **22030** can contact the anvil **22060** directly after being exposed to one or more medicaments in the tissue thickness compensator **22120** thereby reducing the possibility that medicaments may be wiped off the staple legs before they re-enter the tissue T. In some circumstances, the staple legs can re-enter the tissue thickness compensator **22120** as the staple legs are being deformed downwardly such that the staple legs can be re-exposed to the medicaments before re-entering the tissue T, for example. In various embodiments, similar to the above, the second film **22127** can comprise a plurality of projections **22122**, for example, which can be snugly received within the staple cavities **22062** in order to retain the tissue thickness compensator **22120** to the anvil **22060**, for example.

In various embodiments, referring now to FIGS. **120** and **121**, an end effector of a surgical stapling instrument can comprise a tissue thickness compensator, such as compensator **22220**, for example, which can comprise a plurality of cavities **22222** aligned with the staple forming pockets **22062** of the anvil **22060**. In at least one embodiment, the compensator **22220** can be comprised of a first, or bottom, layer **22226** and a second, or top, layer **22227** wherein the first layer **22226** and/or the second layer **22227** can comprise a plurality of raised portions or partial bubbles which can define the cavities **22222**. As illustrated in FIG. **120**, the compensator **22220** can be attached to the anvil **22060** such that the cavities **22222** are aligned, or at least substantially aligned, with the staple forming pockets **22062** of the anvil **22060**. In various embodiments, each cavity **22222** can include one or more medicaments contained therein, such as, for example, oxidized regenerated cellulose, calcium, and/or alginate. In use, in certain embodiments, each cavity **22222** can be in a sealed, unpunctured state prior to being punctured by the staples **22030** ejected from the staple cartridge **22000**, for example. After the legs of the staples **22030** have passed through the tissue T, referring now to FIG. **121**, each staple leg can pierce and penetrate the first layer **22226** and enter into a cavity **22222** where the staple leg can then pass through one or more medicaments contained therein before piercing and penetrating the second layer **22227**. Similar to the above, the legs of the staples **22030** can then contact the anvil **22060**.

In various embodiments, the cavities **22222** can maintain the one or more medicaments stored therein in a dry or an at least substantially dry state before being ruptured. After a cavity **22222** has been ruptured, a fluid, such as blood, for example, can enter into the cavity **22222** and mix with the one or more medicaments. In at least one embodiment, the mixture of the fluid with a medicament can cause the medicament to expand within the cavity **22222** wherein, in at least one such embodiment, the medicament can comprise at least one hydrogel, for example. In certain embodiments, the medicament can comprise at least one haemostatic material, for example. In various embodiments, the first layer **22226** and/or the second layer **22227** can be comprised of a flexible material which can stretch to accommodate the expansion of the medicament. In at least one embodiment, the layers **22226**, **22227** can be comprised of a CAP/GLY material, for example. In any event, the expansion of the medicament can apply a compressive force to the tissue T captured within and/or positioned around the staples **22030**, for example. In various circumstances, the expansion of the medicament can cause the cavities **22222** to burst. In certain embodiments, a first group of cavities **22222** can comprise a first medicament therein while a second group of cavities **22222** can comprise a second medicament therein, for example. In at least one such embodiment, the first medicament can be configured to expand a first amount and/or at a first rate while the second medicament can be configured to expand a second amount and/or at a second rate, for example, wherein the first amount can be different than the second amount and/or the first rate can be different than the second rate. Further to the above, in various embodiments, one or more cavities **22222** can include two or more medicaments stored in each cavity wherein the medicaments can comprise a first medicament and a second medicament, for example. In certain embodiments, a cavity **22222** can maintain the first medicament and the second medicament in a dry, or an at least substantially dry, state before being ruptured. After the cavity **22222** has been ruptured, as described above, blood, for example, can enter into the cavity **22222** and mix with the first and second medicaments wherein, in at least one embodiment, the first and second medicaments can form a gel which expands.

In various embodiments, referring now to FIGS. **122-124**, a tissue thickness compensator, such as compensator **22320**, for example, can comprise a plurality of first cavities **22322a** and a plurality of second cavities **22322b** which can be aligned with staple forming pockets **22062a** and **22062b**, respectively. In at least one embodiment, referring primarily to FIG. **123**, the staple forming pockets **22062a** and **22062b** may be defined in separate stepped surfaces on the anvil **22060**. More particularly, the forming pockets **22062a** can be defined in first surfaces **22069a** of anvil **22060** and the forming pockets **22062b** can be defined in second surfaces **22069b** wherein the first surfaces **22069a** can be positioned offset, or higher, with respect to the second surfaces **22069b**, for example. In various embodiments, the first cavities **22322a** of the tissue thickness compensator **22320** can be larger than the second cavities **22322b** wherein, in at least one such embodiment, the first cavities **22322a** can extend higher than the second cavities **22322b**. As a result of the above, the first cavities **22322a** can extend upwardly into the first staple forming pockets **22062a** while, concurrently, the second cavities **22322b** can extend upwardly into the second staple forming pockets **22062b**. In various embodiments, each of the first cavities **22322a** can be configured to contain a larger quantity of a medicament than the second cavities **22322b**, for example. In other embodiments, the first cavities **22322a** and the second cavities **22322b** can contain the same, or at least

substantially the same, amount of medicament therein even though the cavities **22322a** and **22322b** may have different sizes.

In various embodiments, further to the above, the first cavities **22322a** can be arranged in certain rows while the second cavities **22322b** can be arranged in different rows. In certain embodiments, a tissue thickness compensator can comprise cavities aligned with each forming pocket while, in other embodiments, referring to FIG. **130**, a tissue thickness compensator, such as compensator **22420**, for example, may comprise cavities aligned with only some of the forming pockets. In various embodiments, referring again to FIG. **123**, the compensator **22320** can be attached to the anvil **22060**. In at least one embodiment, the cavities **22322a** and/or the cavities **22322b** can be configured such that fit snugly within staple forming pockets **22062a** and/or **22062b**, respectively. In certain embodiments, the compensator **22320** can be assembled to the anvil **22060** such that the second layer **22327** of the compensator **22320** is positioned against the second surfaces **22069b** of the anvil **22060**. In certain other embodiments, referring now to FIGS. **125** and **126**, the compensator **22320** can be positioned adjacent to the anvil **22060** such that the compensator **22320** can abut the anvil **22060** when the anvil **22060** is displaced toward the staple cartridge **22000** to compress the tissue **T** therebetween. Once the staples **22030** have been fired from the staple cartridge **22000** and deformed by the anvil **22060**, referring now to FIG. **127**, the compensator **22320** can be trapped against the tissue **T** by the staples **22030** and the anvil **22060** can be moved away from the compensator **22320**. In certain circumstances, referring now to FIG. **128**, one or more of the staples **22030** may not be properly deformed by the anvil **22030**. In such circumstances, referring now to FIG. **129**, the cavities in the tissue thickness compensator which overlie the misfired or misformed staples may not be pierced when the staples are fired. In at least one such embodiment, the tissue thickness compensator may be comprised of a bioabsorbable material which can dissolve and subsequently release the medicament contained in the unpierced cavities.

In various embodiments, further to the above, the first cavities **22322a** and/or the second cavities **22322b** of the tissue thickness compensator **22320** can comprise a gas, such as air, carbon dioxide, and/or nitrogen, for example, sealed therein. In certain embodiments, the cavities **22322a** and/or **22322b** can comprise bubbles which can be popped when the staples **22030** are fired through the cavities **22322a** and **22322b** to release the gas contained therein. In at least one embodiment, such popping can provide an audio feedback to the surgeon that the cavities **22322a** and **22322b** are being ruptured. In some circumstances, however, some of the staples **22030** may be misfired, as described above, and the cavities **22322a** and **22322b** associated therewith may not be popped. In various circumstances, the surgeon can scan the stapled tissue for any unpopped bubbles, or cavities **22322a** and **22322b**, and determine whether any corrective action needs to be taken.

As discussed above, referring now to FIG. **131**, a surgical stapling instrument can comprise a firing member, such as firing member **22080**, for example, which can include a cutting member, or cutting edge, **22081** which can be advanced through the tissue **T** and one or more tissue thickness compensators as the firing member **22080** is advanced through the cartridge **22000** to deploy the staples **22030** therefrom. In various embodiments, referring primarily to FIG. **133**, a compensator, such as compensator **22520**, for example, can be attached to the anvil **22060** of the surgical stapling instrument wherein the anvil **22060** can include a knife slot **22061** sized

and configured to receive at least a portion of the cutting member **22081**. Similarly, the staple cartridge **22000** can comprise a knife slot **22011** which can also be sized and configured to receive at least a portion of the cutting member **22081**. In various embodiments, referring again to FIG. **131**, the compensator **22520** can comprise one or more cavities, such as cavities **22522**, for example, positioned along a cutting line **22521** of the compensator **22520** wherein the cavities **22522** can be aligned with the knife slot **22061** defined in the anvil **22060**. As the cutting member **22081** is progressed distally through the staple cartridge **22000** to deploy the staples **22030**, the cutting member **22081** can incise the tissue **T** and the cavities **22522** of the compensator **22520**. Similar to the above, referring primarily to FIG. **132**, each cavity **22522** can define a sealed cavity **22524** which can contain one or more medicaments **22525** therein. In at least one embodiment, one or more of the cavities **22522** can be configured to contain a fluid which can be released when the cavities **22522** are at least partially incised by the cutting member **22081**. In various circumstances, the cutting member **22081** can sequentially incise the cavities **22522** and, as a result, sequentially release the medicaments contained therein.

In various embodiments, referring primarily to FIG. **133**, the compensator **22520** can comprise lateral projections, or wings, **22529** that extend along the sides thereof. In at least one embodiment, the projections **22529** can be secured to the anvil surfaces **22069a** and/or anvil surfaces **22069b** utilizing one or more adhesives, for example. In certain embodiments, the projections **22522** can be sized and configured to fit snugly within the knife slot **22061** of the anvil **22060** such that, in at least one such embodiment, the projections **22522** can retain the compensator **22520** to the anvil **22060**. In various embodiments, the lateral projections **22529** can be sized and configured such that they extend over, or overlie, the staple forming pockets **22062b** and/or the staple forming pockets **22062a**. In certain other embodiments, referring now to FIGS. **134** and **135**, a compensator **22620** can comprise lateral projections **22629** that do not extend over, or overlie, the staple forming pockets **22062a** and **22062b** of the anvil **22060** and/or any other staple forming pockets, for example. In at least one such embodiment, the compensator **22620** may not be captured within a staple **22030** ejected from the staple cartridge **22030**. In any event, referring again to FIG. **131**, the cutting member **22081** can transect the compensator **22520** as the compensator **22520** is being secured to the tissue **T** by the staples **22030**. In such embodiments, the compensator **22520** can detach from the anvil **22060** and remain with the tissue **T**. Referring again to the compensator **22620** illustrated in FIGS. **134** and **135**, the staples **22030** may not secure the compensator **22620** to the anvil **22060** and, in at least one embodiment, may remain attached to the anvil **22060** after the cutting member **22081** has transected the compensator **22620**.

In various embodiment, referring now to FIGS. **136** and **137**, an end effector of a surgical stapling instrument can comprise a tissue thickness compensator, such as compensator **22720**, for example, which can be attached to, or can be configured to be attached to, an anvil, such as anvil **22760**, among others. In at least one embodiment, similar to the above, the anvil **22760** can comprise a plurality of staple forming pockets **22762** and a longitudinal knife slot **22761** configured to receive a cutting member therein as the cutting member is advanced through the end effector. In certain embodiments, the compensator **22720** can comprise a first film layer **22726** and a second film layer **22727** which can be attached to one another to define a cavity **22724**. In at least one such embodiment, the first film layer **22726** can be attached to the second film layer **22727** along a sealed outer

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perimeter 22728 wherein the sealed outer perimeter 22728 can contain at least one medicament 22725 in the cavity 22724, for example. As illustrated in FIG. 137, the cavity 22724 and the medicament 22725 can extend under all of the staple cavities 22762 and, in at least one embodiment, the sealed perimeter 22728 can be positioned laterally with respect to the outermost staple cavities 22762. In various embodiments, the compensator 22720 can further comprise a longitudinal rib 22721, for example, which can be configured to extend upwardly into the knife slot 22761. In at least one such embodiment, the rib 22721 can be sized and configured to fit snugly within the knife slot 22761 in order to secure the compensator 22720 to the anvil 22760. In certain embodiments, the rib 22721 can be configured to align or center the compensator 22720 with the anvil 22760. Similarly, referring to FIG. 138, a tissue thickness compensator 22820 can comprise a retention rib 22821 which can be positioned within the knife slot 22761, for example, in order to secure the compensator 22820 to the anvil 22760. Referring again to FIG. 137, as a cutting member is advanced through the knife slot 22761, in various circumstances, the cutting member can transect the rib 22721 and release the compensator 22720 from the anvil 22760. Such a cutting member is depicted in FIG. 138 as part of firing member 22080, for example.

In various embodiments, referring again to FIG. 138, the tissue thickness compensator 22820 can comprise a first layer 22826 and a second layer 22827 which can be configured and arranged to define a plurality of first packets 22824a and a plurality of second packets 22824b. In at least one embodiment, each of the first packets 22824a can be configured to contain a first medicament and each of the second packets 22824b can be configured to contain a second medicament, wherein the second medicament can be different than the first medicament. In various embodiments, the first packets 22824a and the second packets 22824b can be arranged in an alternating arrangement. In at least one such embodiment, the first packets 22824a and the second packets 22824b can extend laterally across the tissue thickness compensator 22820 such that a second packet 22824b is positioned intermediate two first packets 22824a and a first packet 22824a is positioned intermediate two second packets 22824b, for example. As the cutting member 22080 is progressed through the compensator 22820, as illustrated in FIG. 138, the cutting member 22080 can transect a first packet 22824a, followed by a second packet 22824b, followed by a first packet 22824a, followed by a second packet 22824b, and so forth. Correspondingly, in such embodiments, the cutting member 22080 can sequentially release the first medicament contained in a first packet 22824a and the second medicament contained in a second packet 22824b in an alternating arrangement, for example. In embodiments where the first packets 22824a and the second packets 22824b are positioned adjacent to one another, the first medicament can be configured to mix with the second medicament when they are released from their respective first packets 22824a and second packets 22824b. In at least one such embodiment, the advancement of the cutting member through the compensator 22820 can mix the first medicament with the second medicament.

In various embodiments, further to the above, the first medicament can comprise a first powder while the second medicament can comprise a second powder. In at least one embodiment, the first medicament and/or the second medicament can be comprised of a haemostatic material, oxidized regenerated cellulose, alginate, and/or calcium, for example. In certain embodiments, the first medicament and/or the second medicament can comprise a fluid. In at least one embodiment, one or more of the first packets 22824a and/or one or

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more of the second packets 22824b can comprise a lubricant which can reduce the force needed to advance the firing member 22080 through the compensator 22820 and/or the tissue T. In various embodiments, the first film layer 22826 and/or the second film layer 22827 can be comprised of a bioabsorbable material, such as PDS, for example. In certain embodiments, the first film layer 22826 and the second film layer 22827 can be attached to one another such that the first packets 22824a are sealed from the second packets 22824b prior to being incised by the firing member 22080. In certain embodiments, the first packets 22824a and/or the second packets 22825b can comprise a certain burst strength in order to withstand a certain burst pressure. More particularly, when an anvil, such as anvil 22760, for example, moves the compensator 22820 toward a staple cartridge positioned opposite the anvil 22760, the packets 22824a, 22824b can be positioned against the tissue positioned intermediate the packets 22824a, 22824b and the staple cartridge wherein the anvil 22760 can then be pushed, or clamped, downwardly toward the staple cartridge in order to compress the tissue positioned therebetween. In such circumstances, the packets 22824a, 22824b may be subjected to compressive pressures. In some circumstances, it may be desirable for the packets 22824a and/or packets 22824b to remain intact until they are incised by the cutting member 22080 and/or punctured by staples fired from the staple cartridge. In certain other circumstances, it may be desirable for the packets 22824a and/or the packets 22824b to burst from the compressive clamping load applied thereto.

As discussed above, the first packets 22824a and the second packets 22824b can extend laterally across the compensator 22820. In various embodiments, the first packets 22824a can extend along transverse axes 22823a while the second packets 22824b can extend along transverse axes 22823b, for example. In at least one embodiment, the first axes 22823a and/or the second axes 22823b can be perpendicular, or at least substantially perpendicular, to a longitudinal axis 22083 of the compensator 22820. In at least one such embodiment, the longitudinal axis 22083 can define the cutting path of the firing member 22080. In certain embodiments, the first axes 22823a and/or the second axes 22823b may not be perpendicular to the longitudinal axis 22083 and may be skew with respect to the longitudinal axis 22083. In various embodiments, as discussed above, the first packets 22824a and the second packets 22824b can be arranged in an alternating arrangement. In certain other embodiments, any other suitable arrangement of the first packets 22824a and the second packets 22824b may be utilized. For instance, a sequence of packets arranged in a tissue thickness compensator could include a first packet 22824a, a second packet 22824b, a second packet 22824b, and a first packet 22824a. In certain embodiments, a tissue thickness compensator can further comprise a plurality of third packets comprising a third medicament which is different than the first medicament and the second medicament. In at least one such embodiment, the first packets, the second packets, and the third packets can be arranged in an alternating arrangement. For instance, a sequence of packets arranged in a tissue thickness compensator could include a first packet, followed by a second packet, which is followed by a third packet, for example.

In various embodiments, referring again to FIG. 138, the first packets 22824a and/or the second packets 22824b of the tissue thickness compensator 22820 can define U-shaped, or at least substantially U-shaped, cross-sections, for example. In certain embodiments, referring now to FIG. 139, the packets 22924 of a tissue thickness compensator 22920 can define circular, or at least substantially circular, cross-sections, for

example. In some embodiments, referring now to FIG. 140, the packets **23024** of a tissue thickness compensator **23020** can define oval and/or elliptical cross-sections, for example. In various embodiments, referring again to FIG. 138, the first cavities **22824a** and the second cavities **22824b** can comprise symmetrical, or at least nearly symmetrical, configurations which are defined in parallel, or at least substantially parallel, rows. In certain other embodiments, referring now to FIG. 141, a tissue thickness compensator, such as compensator **23120**, for example, can comprise asymmetrical cavities **23122** defined therein which can have an irregular and/or non-repeating pattern, for example. In at least one such embodiment, each of the cavities **23122** can contain one or more different medicaments therein.

In various embodiments, referring now to FIG. 142, a tissue thickness compensator, such as tissue thickness compensator **23220**, for example, can comprise a casing **23226** which defines a cavity **23224** therein and a material **23225** positioned within the cavity **23224**. In certain embodiments, the casing **23226** can be comprised of a resorbable polymer, PDS, PGA, PLLA, Cap Gly, and/or PCL, for example, while the material **23225** could be comprised of a haemostatic agent, oxidized regenerated cellulose, Hercules, fibrin, and/or thrombin, for example, which can take any suitable form such as a powder, a fiber, and/or a gel, for example. In at least one embodiment, the casing **23226** can be manufactured utilizing an extrusion process. In such embodiments, the casing **23226** can comprise a constant, or an at least substantially constant, cross-section along the length thereof which can be created without having to weld a seam together. In at least one such embodiment, the cavity **23224** can be defined by a sidewall extending around the entire perimeter thereof without openings defined therein. In certain embodiments, the casing **23226** can be comprised of a mesh and/or a straw-like material having openings defined therein. In at least one embodiment, openings can be cut in the casing **23226** by a laser cutting process and/or a die cutting process, for example.

As part of manufacturing the material **23225**, referring now to FIGS. 145-147, a yarn strand can be created utilizing fibers and/or a fibrous material, such as oxidized regenerated cellulose, for example. In certain embodiments, longer fibers **23325**, depicted in FIG. 145, and shorter fibers **23425**, depicted in FIG. 146, can be mixed together as illustrated in FIG. 147 to form the yarn strand of material **23225**. In various embodiments, the yarn strand can be drawn and/or placed under tension in order to stretch the fibers contained therein in a longitudinal direction. In certain embodiments, referring now to FIG. 148, the yarn strand of material **23225** can be fluffed by graspers **23290** which can grasp and twist the material **23225** to increase the volume of the yarn strand. In at least one such embodiment, the graspers **23290** can fluff the material **23225** as the yarn strand is moving relative to the graspers **23290**, for example. In some embodiments, referring again to FIG. 148, cutting members **23291** could be utilized to make small incisions and/or micro-cuts, for example, in the yarn strand of material **23225**. Similar to the above, the cutting members **23291** can cut the material **23225** as the yarn strand is moving relative to the cutting members **23291**. In certain embodiments, the yarn strand of material **23225** can be fluffed before the above-described incisions are made while, in other embodiments, the yarn strand of material **23225** could be incised before it is fluffed.

Once the yarn strand of material **23225** has been suitably prepared, the material **23225** can be positioned within the casing **23226**. In at least one embodiment, referring now to FIG. 149, two or more casings **23226** could be formed together as part of an extrusion process, discussed above,

wherein the casings **23226** can be connected together as part of a tube **23227**. In various embodiments, the yarn strand of material **23225** can be positioned within, or drawn into, the cavity **23224** defined in the tube **23227**. In at least one embodiment, the yarn strand of material **23225** can be positioned adjacent to and/or within a first open end **23221** of the cavity **23224** wherein a grasper **23292** can be inserted through a second open end **23222** of the cavity **23224**. The grasper **23292** can then be pushed through the cavity **23224** until the jaws **23292a** of the grasper **23292** pass through, and/or are positioned relative to, the first open end **23222** such that grasper jaws **23292a** can be manipulated to grasp the yarn strand of material **23225**. In certain embodiments, a grasper may comprise a hook member, for example, which can be configured to grasp the yarn strand of material **23225**. In any event, once the grasper **23292** has sufficiently grasped the yarn strand of material **23225**, the grasper **23292** can be drawn back into the cavity **23224** in order to pull the yarn strand of material **23225** into the cavity **23224**. In various embodiments, the grasper **23292** can be configured to twist the yarn strand of material **23225** before, during, and/or after the yarn strand is pulled into the tube **23227**.

Once the yarn strand of material **23225** has been suitably positioned within the tube **23227**, the grasper **23292** can then be operated to release the yarn strand of material **23225**. In various embodiments, the yarn strand can be released before the yarn strand has been pulled through the second open end **23222** of the tube **23227** while, in other embodiments, the yarn strand can be released after the yarn strand has been pulled through the second open end **23222**, as illustrated in FIG. 150. In certain circumstances, the yarn strand can be pulled through the second open end **23222** such that, when the yarn strand is released, the yarn strand can shrink, or spring back, into the tube **23227** through the second open end **23222**. In various circumstances, the yarn strand can be cut at a location adjacent to the first open end **23221** such that, similar to the above, the yarn strand can shrink, or spring back, into the tube **23227** through the first open end **23222**. In various circumstances, further to the above, the grasper **23292** can apply a tension force to the yarn strand of material **23225** such that when the grasper **23292** releases the yarn strand and/or when the yarn strand is cut, the tension force within the yarn strand can be relieved thereby allowing the yarn strand to contract.

Once the yarn strand of material **23225** has been sufficiently positioned within the tube **23227**, referring now to FIG. 151, the tube **23227** and the material **23225** can be cut into a plurality of segments, wherein each segment can be made into a tissue thickness compensator **23220**, for example. In various embodiments, the cavity **23224** extending through the cover **23226** of each such segment can comprise an open end on opposite ends thereof. In at least one such embodiment, one or both of the open ends can be closed and/or sealed by a heat-staking, heat-welding, and/or laser welding process, for example. Referring to FIG. 152, a segment comprising a cover **23226** and a portion of the material **23225** therein can be positioned within a die configured to close and/or seal the open ends of the cover **23226**. More particularly, in at least one embodiment, the die can comprise a base **23294** and a movable portion **23296**, for example, wherein the segment can be positioned within a cavity **23295** defined in the base **23294**. Once positioned, the movable portion **23296** can be moved downwardly to apply a force to the segment. In various embodiments, heat can be applied to the segment via the base **23294** and/or the movable portion **23296** wherein the heat and/or the force applied to the segment can distort the cover **23226**. More specifically, in at least

one embodiment, the movable portion **23296** can define a pocket **23297** which can be contoured to apply a clamping force to certain portions of the cover **23226**, such as the open ends thereof, in order to close, flatten, and/or neck down such portions of the tissue thickness compensator **23220**. For instance, the pocket **23297** can be configured to form the closed ends **23228** of the tissue thickness compensator **23220** and flatten the portion of the tissue thickness compensator **23220** positioned intermediate the closed ends **23228**. After the tissue thickness compensator **23220** has been suitably formed, the movable portion **23296** can be moved to an open position and the tissue thickness compensator **23220** can be removed from the die. In various embodiments, the tissue thickness compensator **23220** can then be positioned in a cooling container wherein the compensator **23220** can be permitted to cool to room temperature and/or any other suitable temperature.

In certain alternative embodiments, further to the above, the tube **23227** can be positioned within a heat-forming die after the material **23225** has been positioned therein. After the tube **23227**, and the material **23225** positioned therein, have been formed, the tube **23227** and the material **23225** can then be segmented into a plurality of tissue thickness compensators **23220**, for example. In various embodiments, referring again to FIG. **142**, the tissue thickness compensator **23220** can comprise lateral wings, or clips, **23229** which can be configured to be attached to the anvil **22060**, for example. In at least one such embodiment, the lateral wings **23229** can be formed in the cover **23226** when the tissue thickness compensator **23220** is formed between the die portions **23294** and **23296**, as described above. Referring now to FIG. **143**, a tissue thickness compensator **23320** can comprise lateral wings **23329** extending from cover **23326**. In certain embodiments, referring now to FIG. **144**, a tissue thickness compensator **23420** can comprise a cover **23426** having one or more lateral flexible joints **23428**, for example, which can permit the cover **23426** to flex and flatten when it is subjected to a compressive pressure in the heat-forming die described above. In various embodiments, as a result of the above, the tissue thickness compensator **23220** may not comprise lateral seams. In such embodiments, referring again to FIG. **142**, the material **23225** may extend to the lateral edges of the anvil **22060**, for example.

As described above, a yarn strand can be pulled through a tube and then cut to length to form one or more tissue thickness compensators. In various embodiments, further to the above, a yarn strand can be pulled or pushed through a tube utilizing a rigid strand of material. In at least one embodiment, a rigid strand of polymer material, such as PCL, for example, can be heated above its glass transition temperature and stretched into a deformed shape. In at least one such embodiment, the rigid strand can comprise an undeformed serpentine shape which, when stretched into its deformed shape, can comprise a straight, or at least substantially straight, shape, for example. Thereafter, the rigid strand can be cooled below the glass transition temperature of the material while the rigid strand is constrained so that the rigid strand can maintain its deformed shape. Once the rigid strand is in its deformed shape, in various embodiments, ORC fibers, for example, can be formed around the rigid strand. In certain embodiments, an ORC yarn strand, for example, can be wound around, flocked, and/or folded over the rigid strand. Alternatively, the rigid strand can be inserted into ORC fibers, for example. In certain embodiments, the rigid strand can comprise a sticky surface which can be rolled and/or dipped within the ORC fibers. In any event, the rigid strand and the ORC fibers can then be inserted into a tube, similar to the

above, and reheated above the glass transition temperature of the rigid strand. In such circumstances, the rigid strand can be unconstrained, or at least substantially unconstrained, and can be permitted to return, or at least substantially return, to its original undeformed shape. In at least one such embodiment, the rigid strand can contract when returning to its original shape and retract the ORC fibers into the tube. In certain embodiments, the center of the tube can be clamped to hold the rigid strand and the ORC fibers in the center of the tube as the rigid tube contracts. Similar to the above, the ends of the tube can be sealed to enclose the rigid strand and the ORC fibers therein.

In various embodiments, referring now to FIG. **244**, a tissue thickness compensator **33320** can comprise a shell **33326**, a compressible core positioned within the shell **33326**, and closed ends **33328** which can be configured to contain the compressible core within the shell **33326**. In at least one embodiment, further to the above, the shell **33326** can be produced from a continuous extruding process and can comprise a continuous cross-sectional shape along the length thereof. In certain embodiments, referring now to FIGS. **245-247**, a tissue thickness compensator **33420** can comprise a shell **33426**, a cavity **33424** defined in the shell **33426**, and a core **33425** positioned within the cavity **33424**. In at least one such embodiment, the shell **33426** can comprise a film body formed from a continuous extruded shape and the core **33425** can comprise a fibrous medicament core, such as ORC, for example. In at least one embodiment, the shell **33426** can comprise one or more flexible legs **33423** which can be configured to extend into a knife slot **22063** defined in the anvil **22060** and releasably retain the tissue thickness compensator **33420** to the anvil **22060**. In certain embodiments, referring now to FIGS. **248-250**, a tissue thickness compensator **33520** can comprise a shell **33526**, a cavity **33524** defined in the shell **33526**, and a core **33425** positioned within the cavity **33524**. In at least one such embodiment, the shell **33526** can comprise a film body formed from a continuous extruded shape and the core **33425** can comprise a fibrous medicament core, such as ORC, for example. In at least one embodiment, the shell **33526** can comprise one or more retention members **33528** which can be configured to extend around the outside surface of the anvil **22060** and releasably retain the tissue thickness compensator **33520** to the anvil **22060**. In at least one such embodiment, referring primarily to FIG. **250**, the shell **33526** can comprise movable portions **33527** and a gap **33523** defined between the movable portions **33527** wherein, after the tissue thickness compensator **33520** has detached from the anvil **22060**, the movable portions **33527** can spring open to expose the core **33425** contained therein. In certain embodiments, referring now to FIGS. **251-252**, a tissue thickness compensator **33620** can comprise a shell **33626**, a cavity **33424** defined in the shell **33626**, and a core **33425** positioned within the cavity **33424**. In at least one such embodiment, the shell **33626** can comprise a film body formed from a continuous extruded shape and the core **33425** can comprise a fibrous medicament core, such as ORC, for example. In at least one embodiment, the shell **33626** can comprise a thin section **33623** which can be aligned with the knife slot **22063** defined in the anvil **22060** such that a cutting member passing through the tissue thickness compensator **33620** can pass through the thin section **33623** and reduce the force or energy needed to transect the tissue thickness compensator **33620**. In certain embodiments, referring now to FIGS. **253-254**, a tissue thickness compensator **33720** can comprise a shell **33726**, a cavity **33424** defined in the shell **33726**, and a core **33425** positioned within the cavity **33424**. In at least one such embodiment, the shell **33726** can comprise a film body formed from a continu-



ous extruded shape and the core **33425** can comprise a fibrous medicament core, such as ORC, for example. In at least one embodiment, the shell **33726** can comprise one or more retention members **33723** which can be configured to wrap around the outside surface of the anvil **22060** and releasably retain the tissue thickness compensator **33720** to the anvil **22060**. In certain embodiments, referring now to FIGS. **255-256**, a tissue thickness compensator **33820** can comprise a shell **33826**, a cavity **33424** defined in the shell **33826**, and a core **33425** positioned within the cavity **33424**. In at least one such embodiment, the shell **33826** can comprise a film body formed from a continuous extruded shape and the core **33425** can comprise a fibrous medicament core, such as ORC, for example. In at least one embodiment, the shell **33826** can comprise a substantially rectangular cavity **33424** and a substantially flat tissue contacting surface **33829** as opposed to the arcuate cavity **33424** and tissue contacting surface depicted in FIG. **254**, for example. In certain embodiments, referring now to FIGS. **257-258**, a tissue thickness compensator **33920** can comprise a shell **33926**, a plurality of cavities **33924** defined in the shell **33926**, and a core **33925** positioned within each of the cavities **33924**. In at least one such embodiment, the shell **33926** can comprise a film body formed from a continuous extruded shape and the cores **33925** can each comprise a fibrous medicament core, such as ORC, for example. In certain embodiments, the cores **33925** can be comprised of different materials. In at least one embodiment, the shell **33926** can comprise one or more retention members **33923** which can be configured to extend into the knife slot **22063** of the anvil **22060**.

Referring now to FIG. **153**, a tissue thickness compensator can be formed utilizing a folding process. In various embodiments, a material **23525**, such as oxidized regenerated cellulose, for example, can be placed on a cover sheet **23526** which can be folded and then sealed in order to encapsulate the material **23525**. In at least one such embodiment, the cover sheet **23526** can be comprised of cap gly, for example. In certain embodiments, a continuous process can be utilized in which the cover sheet **23526** can be passed under a hopper **23592** which is configured to dispense the material **23525** onto the cover sheet **23526**. In at least one such embodiment, the cover sheet **23526** can be flattened between a roller **23591** and an anvil **23590** before the material **23525** is placed onto the cover sheet **23526**. In certain embodiments, the material **23525** may be placed on one side, or half, of the cover sheet **23526** wherein the other side, or half, of the cover sheet **23526** can be folded, or flipped, over the material **23525**. Before, during, and/or after the material **23525** has been placed on the cover sheet **23526**, the cover sheet **23526** can be folded, or at least partially folded. In various embodiments, the anvil **23590**, for example, can comprise a cam surface **23594** which can be configured to lift an edge or side of the longitudinally moving cover sheet **23526** and then fold the cover sheet **23526** in half, for example. In at least one embodiment, the cam surface **23594** can comprise a three-dimensional cam, or barrel cam, which progressively lifts and turns a portion of the cover sheet **23526** as the cover sheet **23526** passes by the cam surface **23594**.

After the cover sheet **23526** has been folded over the material **23525**, the folded cover sheet **23526** and the material **23525** positioned therein can pass through a die **23593** which can, in at least one embodiment, compress and/or compact the folded cover sheet **23526** and the material **23525** to form a tube **23527**. In certain embodiments, the edges of the folded cover sheet **23526** can be sealed closed utilizing any suitable process such as thermal welding and/or laser welding, for example. In various embodiments, the tube **23527** can be

further flattened by one or more rollers **23595**, for example, before the sidewall of the tube **23527** has been sealed. In certain embodiments, the tube **23527** can be further flattened by one or more rollers after the sidewall of the tube **23527** has been sealed. In any event, the tube **23527** can be segmented into portions to create separate tissue thickness compensators. In various embodiments, the ends of the tissue thickness compensators can be sealed utilizing any suitable process such as thermal welding and/or laser welding, for example, while, in other embodiments, one or both of the ends of the tissue thickness compensator can remain in an open configuration, for example.

In various embodiments, referring now to FIG. **154**, a compensator can be attached to an anvil, such as anvil **22060**, for example, wherein the compensator can be configured to store at least one medicament therein. In at least one embodiment, a compensator **23620** can comprise a central body portion **23626** and lateral attachment portions **23628** which can be configured to be attached to the anvil **22060**. In certain embodiments, the compensator **23620** can further comprise an array of capillary channels **23627** defined in a tissue contacting surface **23625** of the compensator **23620** wherein the capillary channels **23627** can be configured to store one or medicaments therein. In at least one such embodiment, the medicament can comprise a fluid which, owing to fluid tension forces, can be retained between the sidewalls of the capillary channels **23627**. In various circumstances, the medicament can be applied to the compensator **23620** before the compensator **23620** is attached to the anvil **22060** while, in some circumstances, the medicament can be applied to the compensator **23620** after it has been attached to the anvil **22060**, for example. In any event, the compensator **23620** can be configured to contact tissue positioned between the anvil **22060** and a staple cartridge positioned opposite the anvil **22060** wherein the medicament stored in the capillary channels **23627** can flow onto the tissue. In various circumstances, the medicament can flow within the capillary channels **23627**.

In various embodiments, referring again to the compensator **23620** illustrated in FIG. **154**, the array of capillary channels **23627** can be constructed and arranged in a cross-hatched pattern wherein a first quantity of channels **23627** can extend in a first direction and a second quantity of channels **23627** can extend in a second direction. In at least one embodiment, the first quantity of channels **23627** can intersect and can be in fluid communication with the second quantity of channels **23627**. Referring now to FIG. **155**, a compensator **23920** can comprise a body **23926** which includes an array of capillary channels **23927** defined in a tissue-contacting surface **23925**. In various embodiments, the channels **23927** can be defined along linear paths while, in certain embodiments, the channels **23927** can be defined along non-linear paths. In at least one embodiment, a first quantity of channels **23927** can extend along axes **23923** while a second quantity of channels **23927** can extend along axes **23924**, for example, wherein the axes **23923** can extend in different directions than the axes **23924**. In various embodiments, the axes **23923** can be perpendicular, or at least substantially perpendicular, to the axes **23924** wherein, in at least one embodiment, the channels **23627** can define islands **23922** therebetween. In at least one such embodiment, the top surfaces of the islands **23922** can define the tissue contacting surface **23925** of the compensator **23920**. In various embodiments, the compensator **23920** can comprise a longitudinal axis **23921** and the channels **23627** can extend in directions which are transverse or skew with respect to the longitudinal axis **23921**. In certain embodiments, referring again to FIG. **154**, a compensator **23720** can comprise a body **23726** and a



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plurality of capillary channels **23727** defined in the body **23726**. In at least one embodiment, the compensator **23720** can further comprise a longitudinal channel **23721** which can be in fluid communication with the capillary channels **23727**. In various embodiments, one or medicaments can be stored in the longitudinal channel **23721** wherein the medicaments can flow between the channel **23721** and the capillary channels **23727**, for example. In at least one embodiment, the channel **23721** can define a longitudinal protrusion which can extend upwardly into a longitudinal knife slot **22061** defined in the anvil **22060**.

As discussed above, referring again to FIG. **154**, an array of capillary channels defined in a compensator can comprise a cross-hatched pattern. In various other embodiments, however, an array of capillary channels can comprise any suitable shape or configuration. For example, referring to compensator **23820** illustrated in FIG. **154**, the channels **23827** defined in the body **23826** of the compensator **23820** can comprise parallel, diagonal channels which converge toward and/or diverge away from a central channel **23821**, for example. Referring now to FIG. **158**, an end effector of a surgical stapling instrument can include a staple cartridge **24000** including a tissue thickness compensator **24010** wherein, in at least one embodiment, the tissue thickness compensator **24010** can include at least one medicament, such as medicament **24001**, for example, therein and/or thereon. Referring now to FIG. **159**, a compensator **24020** attached to an anvil **24060**, for example, can be moved into a closed position in order to place the compensator **24020** in contact with the tissue thickness compensator **24010**. In such circumstances, the medicament **24001**, for example, can be transferred from the tissue thickness compensator **24010** to the compensator **24020**. In at least one embodiment, referring now to FIG. **160**, the compensator **24020** can comprise a tissue contacting surface **24025** which can be brought into contact with the tissue thickness compensator **24010** wherein, in certain embodiments, the medicament **24001** can flow into capillary channels **24027** defined in the tissue contacting surface **24025**. In certain embodiments, referring now to FIG. **157**, the compensator **24020** can include at least one medicament, such as medicament **24002**, for example, thereon and/or therein which can be transferred from the compensator **24020** to the tissue thickness compensator **24010**.

In various embodiments, referring now to FIGS. **240** and **241**, a tissue thickness compensator **33020** can comprise a plurality of channels and/or wells defined in the surface thereof. In at least one embodiment, the tissue thickness compensator **33020** can comprise a longitudinal channel **33026** that extends along a longitudinal axis defined through the tissue thickness compensator **33020**. In at least one such embodiment, the end of the longitudinal channel **33026** can be in fluid communication with the perimeter of the tissue thickness compensator **33020**. The tissue thickness compensator **33020** can further comprise a plurality of wells **33022** and, in addition, a plurality of diagonal channels **33024** which are in fluid communication with the wells **33022** and the longitudinal channel **33026**. In certain embodiments, the tissue thickness compensator **33020** can further comprise a plurality of inlet-outlet channels **33027** which can be in fluid communication with the wells **33022** and the perimeter of the tissue thickness compensator **33020**. In various embodiments, as a result of the above, fluids can flow into and/or out of the tissue thickness compensator **33020** before, during, and/or after it has been implanted against a patient's tissue. In certain embodiments, the pattern of channels **33024**, **33026**, and **33027** and the wells **33022** defined in the tissue-contacting surface **33025** of the tissue thickness compensator **33020**

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can define gripping edges which can be configured to contact the tissue and limit slipping between the tissue thickness compensator **33020** and the tissue. Referring now to the alternative embodiment illustrated in FIGS. **240A** and **241A**, a tissue thickness compensator **33120** can comprise a plurality of circular channels defined in the surface thereof. In various embodiments, the tissue thickness compensator **33120** can comprise concentric circular channels **33127** which comprise openings defined in the perimeter of the tissue thickness compensator **33120**. Similar to the above, fluids can flow into and/or out of the tissue thickness compensator **33120** through the channels **33127**. In at least one embodiment, the tissue thickness compensator **33120** can comprise concentric circular channels **33122** which may not include openings defined in the perimeter of the tissue thickness compensator **33120**. Referring now to the alternative embodiment illustrated in FIGS. **242** and **243**, a tissue thickness compensator **33220** can comprise a plurality of ridges **33227** extending therefrom which can be configured to grip tissue that is positioned against the tissue thickness compensator **33220**. In at least one embodiment, the ridges **33227** can be straight while, in some embodiments, the ridges **33227** can comprise a curved contour, for example. Although the ridges and channels described above may be useful for tissue thickness compensators, in various embodiments, such ridges and channels could be utilized with any suitable bioabsorbable and/or bio-compatible layer.

In various embodiments, a compensator can be comprised of a plurality of layers. In at least one embodiment, the compensator can comprise a first layer and a second layer attached to the first layer, for example. In certain embodiments, the first layer can comprise a tissue contacting surface and a plurality of capillary channels defined in the tissue contacting surface. In at least one embodiment, the first layer can also comprise capillary channels defined in a side which faces the second layer and faces opposite the tissue contacting surface. In certain embodiments, the second layer can comprise capillary channels defined therein. In at least one embodiment, wells can be defined between the first layer and the second layer of the compensator. In various embodiments, the capillary channels can be formed in the layers of the compensator utilizing any suitable process, such as during a molding process in which the layers are formed and/or during a heat-staking process, for example. In at least one embodiment, a heat-staking process can be utilized to attach the layers of the compensator to one another, for example. In at least one such embodiment, the layers can be comprised of a material which can become deformable when heat is applied thereto, such as CAP/GLY (36/64), for example. In any event, in various embodiments, the capillary channels defined in the tissue contacting surface of the compensator can define gripping surfaces therebetween which can improve the grip, or control, that can be applied to tissue positioned between the anvil and the staple cartridge of the surgical stapling instrument. Stated another way, the capillary channels defined in the tissue-contacting surface of a compensator can decrease the area in which the compensator can contact the tissue. In such circumstances, the smaller contact area can result in higher contact pressures between the compensator and the tissue for a given force. In various circumstances, the higher contact pressures can reduce slipping between the compensator and the tissue.

In various embodiments, one or medicaments can be positioned within the capillary channels and/or voids defined within and/or between the first layer and the second layer. In certain embodiments, the plurality of layers comprising a compensator can comprise a pack of therapeutic layers, or therapies. For instance, a first layer can be comprised of a first

medicament and a second layer can be comprised of a second medicament, wherein the first medicament can be different than the second medicament. In at least one such embodiment, capillary channels defined in the first layer can store a third medicament and capillary channels defined in the second layer can store a fourth medicament, wherein the first, second, third, and/or fourth medicaments can be different, for example. In at least one embodiment, the first, second, third, and/or fourth medicaments can be different, for example. In various embodiments, referring now to FIG. 161, a compensator 24120 can comprise a plurality of layers, such as layers 24121-24125, for example. In at least one embodiment, the first layer 24121 and/or the fifth layer 24125 can comprise a flat sheet of material between which the second layer 24122, the third layer 24123, and/or the fourth layer 24124 can be sandwiched. In various embodiments, one or more of the layers 24121-24125 can comprise one or more channels 24127 defined therein. In at least one embodiment, the channels 24127 can extend from one end of the compensator 24120 to the other end and, in certain embodiments, the channels 24127 can extend between one side of the compensator 24120 to the other. In certain other embodiments, the channels 24127 can extend in any suitable direction between any suitable sides and/or ends of the compensator 24120. In various embodiments, referring now to FIGS. 164 and 165, a compensator 24820 can comprise two or more inner layers 24827 which can define lateral channels 24822, for example, which extend from one side of the compensator 24820 to the other. In certain embodiments, referring again to FIG. 161, the channels 24127 defined in one of the layers 24121-24125 can be aligned with the channels defined in a layer positioned adjacent thereto. In some embodiments, the channels 24127 defined in one of the layers 24121-24125 can face, or open toward, a flat surface on a layer positioned adjacent thereto. In various embodiments, referring again to FIG. 161, one or more of the layers 24121-24125 can comprise at least one well 24129 defined therein. In at least one embodiment, the wells 24129 can be in fluid communication with one or more of the channels 24127 defined in the layer. Similar to the above, the wells 24129 can comprise an opening which opens toward, or faces, an adjacent layer wherein the adjacent layer can cover the opening.

In various embodiments, further to the above, the channels 24127 and/or the wells 24129 can be configured to contain one or medicaments therein. In at least one embodiment, the channels 24127 can comprise one or more open ends which can permit a medicament to flow out of the channels 24127. Similarly, in at least one embodiment, the channels 24127 can include one or more openings which can be configured to permit a fluid, such as blood, for example, to flow into the channels 24127. In such embodiments, the fluid can flow into the compensator 24120, absorb at least a portion of a medicament and/or a layer 24121-24125, and then flow out of the compensator 24120. Referring again to FIGS. 164 and 165, the compensator 24820 can comprise apertures 24828 defined in outer layers 24826, for example. In various embodiments, referring again to FIG. 161, the layers 24121-24125 can be comprised of any suitable material, such as a bioabsorbable polymer, PLA, and/or PGA, for example. In certain embodiments, all of the layers 24121-24125 can be comprised of the same material. In certain other embodiments, one or more of the layers 24121-24125 could be comprised of different materials. In various embodiments, one or more of the layers 24121-24125 can include through holes 24128 extending therethrough which can be configured to permit fluids, such as blood, for example, to flow into the channels 24127, wells 24126, and/or between two or more of

the layers 24121-24125, for example. In certain embodiments, one or more of the layers 24121-24125 can be connected to each other utilizing a heat-welding and/or laser-welding process, for example. In such embodiments, the fluid, or fluids, flowing into the compensator 24120 can dissolve the welded portions of the layers 24121-24125 and permit the layers 24121-24125 to separate and/or delaminate. In certain embodiments, one or more of the layers 24121-24125 can be comprised of a material which dissolves at a faster rate and/or a slower rate than the material, or materials, comprising the other layers 24121-24125. In at least one such embodiment, the inner layers 24122-24124 of the compensator 24120 can be comprised of a material which dissolves at a faster rate than the material, or materials, which comprise the outer layers 24121 and 24125, for example. In such embodiments, the compensator 24120 can maintain a consistent, or at least substantially consistent, general shape while the interior of the compensator 24120 is dissolved away. In certain other embodiments, the outermost layers of a compensator can be comprised of a material which dissolves at a faster rate than the material, or materials, which comprise the innermost layers of the compensator, for example. In various embodiments, the layers can comprise sheets of material having a thickness between approximately 1 mil and approximately 4 mils, for example.

In various embodiments, referring now to FIGS. 162 and 163, a compensator, such as compensator 24220, for example, can comprise a support layer 24226 which can be configured to be attached to an anvil, such as anvil 22060, for example, and/or a staple cartridge. In certain embodiments, the compensator 24220 can further comprise a scaffold 24222 attached to the support layer 24226 wherein the scaffold 24222 can comprise a plurality of scaffold layers 24227. In at least one embodiment, the scaffold can comprise a three-dimensional structural matrix, for example. In various embodiments, each of the scaffold layers 24227 can be comprised of a plurality of fibers. In at least one embodiment, referring now to FIG. 166, each scaffold layer 24227 can be comprised of a fiber weave including a first plurality of fibers 24228 extending in a first direction and a second plurality of fibers 24229 extending in a second, or different, direction. In certain embodiments, each fiber weave can comprise a plurality of pockets, or cavities, 24223 wherein the layers 24227, the fibers 24228, 24229, and the cavities 24223 can define a matrix favorable to tissue and cellular ingrowth. In various embodiments, the fibers 24228, 24229, and/or any other suitable fibers, can be comprised of a bioabsorbable material. In at least one embodiment, the fibers can be comprised of a haemostatic agent, bound active agents such as those that are biologically and/or pharmacologically active, and/or support members, for example, which can be interwoven with one another. In any event, the material of the fibers can be selected to induce a desirable biologic response such as cellular migration into the scaffold 24222, ECM secretion, and/or the proliferation of structural support cells, for example.

In various embodiments, further to the above, the support layer 24226 can be configured to structurally support the scaffold 24222. In at least one embodiment, the scaffold 24222 can be attached to the support layer 24226 utilizing one or more bioabsorbable adhesives, for example. Similarly, in certain embodiments, the support layer 24226 can be attached to an anvil or a staple cartridge utilizing one or more biocompatible adhesives, for example. In various embodiments, the layers 24227 of the scaffold 24222 can be arranged, or stacked, in any suitable manner. In certain embodiments, each layer 24227 can comprise a pattern of fibers wherein the layers 24227 can be arranged in the scaffold 24222 such that

the patterns of the layers **24227** are aligned with each other. In at least one embodiment, referring to FIG. **167**, the layers **24228** can be stacked on one another such that the fibers **24228** in a first layer **24227** are aligned with the fibers **24228** in a second layer **24227**. Likewise, the layers **24227** can be stacked on one another such that the fibers **24229** in the first layer **24227** are aligned with the fibers **24229** in the second layer **24227**. In certain embodiments, referring now to FIG. **168**, a scaffold **24422** can comprise a plurality of scaffold layers **24427** wherein the fibers **24429** in each scaffold layer **24427** are oriented in the same direction, such as a longitudinal direction, for example. In certain embodiments, referring now to FIG. **170**, each scaffold layer **24227** can comprise a pattern of fibers wherein the layers **24227** can be arranged in a scaffold **24322** such that the patterns of the layers **24227** are not aligned with each other. In at least one embodiment, the layers **24227** can be stacked on one another such that the fibers **24228** in a first layer **24227** extend in a direction which is transverse to or oblique with the fibers **24228** in a second layer **24227**. Likewise, the layers **24227** can be stacked on one another such that the fibers **24229** in the first layer **24227** extend in a direction which is transverse to or oblique with the fibers **24229** in the second layer **24227**. In certain embodiments, referring now to FIG. **171**, a scaffold **24522** can comprise a plurality of scaffold layers **24427** which are oriented such that the fibers **24229** in each scaffold layer **24427** are oriented in different directions, for example.

In various embodiments, further to the above, a first scaffold layer **24227** of a scaffold **24222**, for example, can be comprised of a first material while a second scaffold layer **24227** of the scaffold **24222** can be comprised of a second, or different, material. In at least one embodiment, the first material can comprise a first medicament while the second material can comprise a second, or different, medicament, for example. In various embodiments, further to the above, a first scaffold layer **24227** of a scaffold **24222**, for example, can comprise a first medicament absorbed into the fibers thereof while a second scaffold layer **24227** of the scaffold **24222** can comprise a second, or different, medicament absorbed into the fibers thereof, for example. In at least one embodiment, the first material can comprise a first medicament while the second material can comprise a second, or different, medicament, for example. In certain embodiments, a scaffold can comprise any suitable number of layers having any suitable density of fibers which are comprised of any suitable number of materials.

Tissue thickness compensators may be installed in a surgical device, such as a surgical cutting and stapling device, for example, utilizing a retainer. The retainer can include a gripping surface and enable a surgeon, nurse, technician, or other person to align one or more of the tissue thickness compensators with features of the surgical instrument, such as an anvil and/or a staple cartridge, for example. In various embodiments, the retainer may include features that align the one or more tissue thickness compensators by engaging a staple cartridge of the surgical instrument. In certain embodiments, the retainer may include features that align one or more tissue thickness compensators by engaging an anvil of a surgical instrument. In certain embodiments, a staple cartridge for the surgical instrument may be included with the retainer and engaging the retainer with the surgical instrument can install the staple cartridge in the surgical instrument and align one or more of the tissue thickness compensators. After the tissue thickness compensators have been aligned with and attached to the surgical instrument, the retainer may be detached from the tissue thickness compensators and then removed from the surgical instrument.

FIGS. **61-67** illustrate an embodiment of a retainer **19000** that may be used to attach a first tissue thickness compensator **19002** to an anvil **19040** and a second tissue thickness compensator **19004** to a staple cartridge **19050** of a surgical stapler, for example. A retainer assembly **19060** can be provided which includes the retainer **19000**, the first tissue thickness compensator **19002**, and the second tissue thickness compensator **19004**. In use, generally, the retainer assembly **19060** may be inserted between the anvil **19040** and a channel configured to support the staple cartridge **19050**. Thereafter, the anvil **19040** can be closed. By closing the anvil **19040**, the anvil **19040** can push downwardly onto the first tissue thickness compensator **19002** such that the first tissue thickness compensator **19002** may be attached to the anvil **19040**. In at least one embodiment, closing the anvil **19040** pushes downwardly on the retainer **19000** and seats the staple cartridge **19050** into the channel of the surgical instrument. When the anvil **19040** is reopened, the first tissue thickness compensator **19002** can detach from the retainer **19000** and when the retainer **19000** is subsequently removed from the surgical device, the retainer **19000** can detach from the second tissue thickness compensator **19004**. The surgical device is then ready for use with the first tissue thickness compensator **19002** attached to the anvil **19040** and the second tissue thickness compensator **19004** attached to the staple cartridge **19050**.

Referring to FIG. **61**, the retainer **19000** may include a grip **19014** by which a person, such as a surgeon, nurse, or technician preparing surgical instruments may grasp the retainer **19000**. The retainer **19000** may include a first surface **19001** on which a first tissue thickness compensator **19002** may be positioned and an opposing second surface **19003** on which a second tissue thickness compensator **19004** may be positioned. In various embodiments, one or more adhesives can be applied to the first surface **19001** and/or the second surface **19003** for attaching the first and second tissue thickness compensators **19002** and **19004** thereto. The retainer **19000** also may include clips that can engage a staple cartridge **19050** of the surgical device, for example. In at least one embodiment, referring to FIG. **64**, the retainer **19000** may include distal clips **19108** configured to engage a recess **19056** at a distal end of the staple cartridge **19050** and/or proximal clips **19106** configured to engage a ridge or edge **19054** on the staple cartridge **19050**.

Referring to FIG. **61**, in various embodiments, the first tissue thickness compensator **19002** may include a retainer-facing surface **19006** and an anvil-facing surface **19010**. The retainer-facing surface **19006** can be attached to the first surface **19001** of the retainer **19000** by adhesives and/or engagement features, for example. The anvil-facing surface **19010** may include at least one adhesive thereon which can attach the first tissue thickness compensator **19002** to the anvil **19040** of the surgical device. For example, the adhesive can comprise an activatable adhesive that may adhere to a staple forming surface **19044** (FIG. **63**) of the anvil **19040**.

Referring to FIGS. **61** and **63-66**, the anvil-facing surface **19010** of the first tissue thickness compensator may include engagement features **19020** that engage similar engagement features **19042** on the anvil **19040**. Thus, in various embodiments, a first retention force can retain the first tissue thickness compensator **19002** to the retainer **19000** and a second retention force can retain the first tissue thickness compensator **19002** to the anvil **19040**. In various embodiments, the second retention force can be greater than the first retention force such that the first tissue thickness compensator **19002**

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can remain attached to the anvil **19040** and separate from the retainer **19000** when the retainer **19000** is removed from the end effector.

Referring again to FIG. **61**, the second tissue thickness compensator **19004** may include a retainer-facing surface **19008** and a staple-cartridge-facing surface **19012**. The retainer-facing surface **19006** can be attached to the first surface **19001** of the retainer **19000** by one or more adhesives and/or engagement features. The staple-cartridge-facing surface **19012** also may include engagement features that engage co-operating engagement features on the staple cartridge **19050**. For example, referring to FIG. **64**, the adhesive may adhere the second tissue thickness compensator **19004** to a staple deck **19052** of the staple cartridge **19050**. The staple-cartridge-facing surface **19012** also may include engagement features that engage co-operating engagement features on the staple cartridge **19050**. Thus, in various embodiments, a first retention force can retain the second tissue thickness compensator **19004** to the retainer **19000** and a second retention force can retain the second tissue thickness compensator **19004** to the staple cartridge **19050**. In various embodiments, the second retention force can be greater than the first retention force such that the second tissue thickness compensator **19004** can remain attached to the staple cartridge **19050** and separate from the retainer **19000** when the retainer **19000** is removed from the end effector.

As shown in FIG. **64**, the retainer assembly **19060** may be attached to a staple cartridge **19050** as indicated by arrow A. As described above, distal clips **19018** on the retainer **19000** may engage a recess **19056** in the staple cartridge and proximal clips **19016** on the retainer may engage the edge or ridge **19054** on the staple cartridge **19050**. At such point, the retainer **19000** is attached to the staple cartridge **19050**, as shown in FIG. **65**, and the second tissue thickness compensator **19004** can be attached to the staple cartridge **19050**. As shown in FIG. **66**, closure of the anvil **19040** of the surgical device in the direction of arrow B may bring a surface **19044** of the anvil, such as a staple-forming surface and/or a tissue contacting surface, for example, into contact with the first tissue thickness compensator **19002**. As described above, the anvil **19040** contacting the first tissue thickness compensator **19002** can cause the first tissue thickness compensator **19002** to become attached to the anvil **19040**.

After the retainer assembly **19060** has been attached to the staple cartridge **19050** and the anvil **19040** has been closed, the first tissue thickness compensator **19002** can be attached to the anvil **19040** and the second tissue thickness compensator **19004** can be attached to the staple cartridge **19050**. As described above, the retention force retaining the first tissue thickness compensator **19002** to the retainer **19000** can be less than the retention force holding the first tissue thickness compensator **19002** to the anvil **19040**. Thus, when the anvil **19040** is reopened, the first tissue thickness compensator **19002** can detach from the retainer **19000** and remain with the anvil **19040**, as shown in FIG. **67**. As also described above, the retention force retaining the second tissue thickness compensator **19004** to the retainer **19000** can be less than the retention force holding the first tissue thickness compensator **19004** to the staple cartridge **19050**. Thus, when the retainer **19000** is removed in the directions of arrows C and D in FIG. **67**, the retainer **19000** can detach from the second tissue thickness compensator **19004**. The surgical stapler shown in FIG. **67** includes the first tissue thickness compensator **19002** attached to the anvil **19040** and the second tissue thickness compensator **19004** attached to the staple cartridge **19050** and is ready for use.

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FIGS. **390-396** show the retainer **19000** being used with a first tissue thickness compensator **19002** and a second tissue thickness compensator **19004**. In various embodiments, the retainer **19000** may also be used with only one of the first tissue thickness compensator **19002** and the second tissue thickness compensator **19004**. For example, the first tissue thickness compensator **19002** may be omitted.

FIGS. **68-70** show an embodiment of a retainer **19100** that can include engagement features **19108** on a surface **19101**. As shown in FIGS. **69** and **70**, the engagement features **19108** on the retainer **19100** engage co-operating engagement features **19109** on a first tissue thickness compensator **19102**.

FIGS. **71** and **72** show an embodiment of a retainer **19200** that may include a surface **19202** configured to align and attach a tissue thickness compensator **19210** to an anvil **19230**. The retainer **19200** may include alignment pegs **19204** extending from the surface **19202**. The retainer **19200** shown in FIGS. **71** and **72** includes four alignment pegs **19204**, but more or fewer alignment pegs **19204** may be present. Referring to FIG. **72**, the tissue thickness compensator **19210** can include a body **19212** that includes holes **19216** that can be located such that they correspond to the locations of the alignment pegs **19204** extending from the retainer **19200**. Each hole **19216** in the tissue thickness compensator **19210** fits over an alignment peg **19204**, and owing to a close fit between the holes **19216** and the pegs **19204**, the tissue thickness compensator **19210** can be aligned with the retainer **19200**. In various embodiments, each hole **19216** may be slightly smaller than its corresponding peg **19204** such that each hole **19216** stretches when placed on its peg **19204**. Such stretching can hold the holes **19216** on the pegs **19204**. In certain embodiments, each hole **19216** may include an adhesive therein to create a releasable bond between the pegs **19204** and the tissue thickness compensator **19210**.

The tissue thickness compensator **19220** may include tabs **19220** extending from a body **19212** of the tissue thickness compensator **19220** which can be configured to be received by slots **19234** in an anvil **19230**. In various embodiments, the slots **19234** in the anvil **19230** may be located in a staple forming surface **19232**, for example. After the retainer **19200** has been attached to a staple cartridge, similar to the embodiments described above, the anvil **19230** can be closed against the tissue thickness compensator **19210** on the retainer **19200**. As the anvil **19230** is closed, referring to FIG. **72**, the tabs **19220** on the tissue thickness compensator **19210** can engage the slots **19234**, thereby attaching the tissue thickness compensator **19210** to the anvil **19230**. Referring primarily to FIG. **71**, each tab **19220** may include a tapered portion **19222** that guides the tab **19220** into the slots **19234** of the anvil **19230**. The tapered portion **19222** can include sloped walls and may increase in cross-sectional area along the length thereof. A base portion **19226** of each tab **19220** may have a smaller cross-sectional area than the largest cross-sectional area of the tapered portion **19222**. In various embodiments, the tapered portion **19222** may comprise a lock surface **19224** wherein, when a tab **19220** enters a slot **19234**, the lock surface **19224** can catch on a lip **19235** in the slot **19234**. As a result, the lock surface **19224** can hold the tab **19220** within the slot **19234** and thereby hold the tissue thickness compensator **19210** to the anvil **19230**. Slots **19228** defined in the tissue thickness compensator **19210** and extending between the tabs **19220** can enable the tabs **19220** to flex inwardly and fit within the slots **19234**. In various embodiments, the tabs **19220** being held with the slots **19234** can define a first retention force that retains the tissue thickness compensator **19210** to the anvil **19230** and the holes **19216** in the tissue thickness compensator **19210** being held on the pegs **19204**.

can define a second retention force. In various embodiments, the first retention force can be greater than the second retention force such that the tissue thickness compensator 19210 can remain attached to the anvil 19230 and separate from the retainer 19200 when the retainer 19200 is removed from the end effector.

The body 19212 of the tissue thickness compensator 19210 in FIGS. 71 and 72 also may define slots 19214 therewithin. The slots 19214 may be aligned along a longitudinal axis of the tissue thickness compensator 19210. For example, the slots 19214 may be arranged on a longitudinal axis such that the slots 19214 are aligned with a longitudinal path of a cutting blade of the surgical device when the tissue thickness compensator 19210 is attached to an anvil 19230. The slots 19214 may reduce the amount of energy required by the cutting blade to cut through the tissue thickness compensator 19210.

FIGS. 73-83 show an embodiment of a retainer 19300 that includes clips 19310 which are configured to retain a tissue thickness compensator 19340 on a first surface 19302 of the retainer 19300. When an anvil 19360 is closed on the retainer 19300, similar to the above, the anvil 19360 can push and displace the clips 19310 outwardly and, as a result, disengage the retainer 19300 from the tissue thickness compensator 19340. In various embodiments, the tissue thickness compensator 19340 can attach to the anvil 19360 when the anvil 19360 is pressed against the tissue thickness compensator 19340 and moved away from the retainer 19300 when the anvil 19360 is reopened.

The retainer 19300 may include staple cartridge mounting clips 19312 and 19314 which can be similar to those described above with respect to FIGS. 61-70. In addition to the first surface 19302 described above, the retainer 19300 also may include a second surface 19304 that may be configured to carry a second tissue thickness compensator. In various embodiments, the second surface 19304 may include an alignment feature, such as, for example, a raised ridge 19308. The raised ridge 19308 may engage a slot in a second tissue thickness compensator and/or a slot in a staple cartridge 19370, for example.

Referring to FIGS. 75-77, in use, the retainer 19300 may be attached to a staple cartridge 19370 by clips 19314 and 19312. The first tissue thickness compensator 19340 can be positioned on the first surface 19302 of the retainer 19300 and can be held in place by clips 19310. Referring primarily to FIGS. 81-83, each clip includes a flat 19313 that can clamp the first tissue thickness compensator 19340 against the first surface 19302 of the retainer 19300. Each clip 19310 can include an inward-facing tapered or curved surface 19311. As the anvil 19360 moves in the direction of arrow E, referring to FIG. 82, edges 19366 of the anvil 19360 can contact the inward-facing curved surfaces 19311 of the clips 19310. As the anvil 19360 continues to move in the direction of arrow E, interference between the edges 19366 of the anvil 19360 and the curved surfaces 19311 of the clips 19310 can push the clips 19310 outwardly in the direction of arrow F, as illustrated in FIG. 82. As the clips 19310 move in the direction of arrow F, the first tissue thickness compensator 19340 is freed from the flats 19313 of the clips 19310.

As the anvil 19360 continues to move in the direction of arrow E, it also contacts and attaches to the tissue thickness compensator 19340. For example, as the anvil 19360 moves in the direction of arrow E, an engagement feature, such as, for example, a raised ridge 19344, on the tissue thickness compensator 19340 engages a channel 19364 in the anvil 19360. The raised ridge 19344 may be configured to have an interference fit with the channel 19364 such that the tissue

thickness compensator 19340 becomes attached to the anvil 19360. The tissue thickness compensator 19340 may include an adhesive that adheres to surfaces of the anvil 19360. In at least one embodiment, the raised ridge 19344 may include an adhesive that adheres to surfaces of the channel 19364. Likewise, surfaces of the body 19342 of the tissue thickness compensator 19340 may include an adhesive that adheres to a surface 19362 of the anvil 19360. After the tissue thickness compensator 19340 is attached to the anvil 19360, the tissue thickness compensator 19340 can lift from the retainer 19300 and remain with the anvil 19360 as the anvil 19360 returns to its open position by moving in the direction of arrow G, as illustrated in FIG. 83.

FIG. 84 shows a cross-sectional side view of an embodiment of a retainer 19400. A first tissue thickness compensator 19410 is positioned on a first side 19402 of the retainer 19400 and a second tissue thickness compensator 19420 is positioned on an opposing second side 19404 of the retainer 19400. The retainer 19400 defines one or more holes 19406 extending therethrough. The first tissue thickness compensator 19410 and the second tissue thickness compensator 19420 are connected through the holes by connectors 19430 which extend through the holes 19406. In various embodiments, the first tissue thickness compensator 19410, the second tissue thickness compensator 19420, and the connectors 19430 all may be formed of a unitary material. For example, the first tissue thickness compensator 19410, the second tissue thickness compensator 19420, and the connectors 19430 may be overmolded onto the retainer 19400. In various other embodiments, the connectors 19430 may be formed as part of one of the tissue thickness compensators, such as, for example, the first tissue thickness compensator 19410. The connectors 19430 may be passed through the holes 19406 and then attached to the remaining tissue thickness compensator, such as, for example, the second tissue thickness compensator 19420. The connectors 19430 may be attached to the second tissue thickness compensator 19420, for example, by using an adhesive or by using an interference fit between an end of the connector and a receiving port (not shown) in the second tissue thickness compensator 19420. In various embodiments, the connectors 19430 may be separate components that are placed into the holes 19406 and to which the first tissue thickness compensator 19410 and the second tissue thickness compensator 19410 may be attached, for example, by using adhesives or interference fits between ends of the connectors 19430 and receiving ports in the first tissue thickness compensator 19410 and the second tissue thickness compensator 19420.

After the retainer 19400 has been placed on a staple cartridge 19450, for example, an anvil 19440 of the surgical device can be moved in the direction of arrow H into a closed position. An adhesive and/or engagement features on a surface 19414 of the first tissue thickness compensator 19410 can attach the first tissue thickness compensator 19410 to the anvil 19440 when the anvil 19440 closes. Likewise, an adhesive and/or engagement features on a surface 19424 of the second tissue thickness compensator 19420 can attach the second tissue thickness compensator 19420 to the staple cartridge 19450. After the anvil 19440 is closed and the first and second tissue thickness compensators 19410 and 19420 are attached to the anvil 19440 and staple cartridge 19450, respectively, the retainer 19400 may be pulled in the direction of arrow I (FIG. 88) to remove the retainer 19400 from between the first tissue thickness compensator 19410 and the second tissue thickness compensator 19420 and to break the connectors 19430. As shown in FIG. 89, after the connectors 19430 are broken and the retainer 19400 has been removed,

the anvil **19440** may be reopened, and the first tissue thickness compensator **19410** will be attached to the anvil **19440** and the second tissue thickness compensator **19420** will be attached to the staple cartridge **19450**.

In various embodiments, a proximal portion **19407** of each hole **19406** in the retainer **19400** may include a cutting edge. When the retainer is pulled in the direction of arrow I (FIG. **88**), a pulling force is transmitted through the proximal portion **19407** of the holes **19406** to break the connectors. A cutting edge at the proximal portion **19407** of each hole **19406** will concentrate the transmitted force on a relatively small area of each connector. As a result, the connectors will break more easily and a lower pulling force may be required to remove the retainer **19400** from between the first tissue thickness compensator **19410** and the second tissue thickness compensator **19420**.

As described above, a retainer assembly can comprise a retainer positioned between a first tissue thickness compensator and a second tissue thickness compensator wherein, after the two tissue thickness compensators have been inserted into and attached to an end effector of a surgical instrument, the retainer can be pulled from between the tissue thickness compensators and removed from the end effector. In certain embodiments, the retainer can provide a barrier between the first and second tissue thickness compensators. Once the retainer is removed from between the first and second tissue thickness compensators, substances in and/or on the first tissue thickness compensator can react with substances in and/or on the second tissue thickness compensator, for example. In some embodiments, one or both of the tissue thickness compensators can include a film that can encase substances within the tissue thickness compensators. In certain embodiments, the films can be attached to the retainer wherein, when the retainer is pulled from between the tissue thickness compensators, as described above, the retainer can pull the films away from the tissue thickness compensators to expose the substances contained therein. At such point, the substances within each of the tissue thickness compensators can interact with each other.

FIGS. **90-100** illustrate an embodiment of a retainer that engages an anvil of a surgical device, such as, for example, a surgical stapler. The retainer may align a first tissue thickness compensator with the anvil and a second tissue thickness compensator with a staple cartridge. Closing the anvil causes the first tissue thickness compensator to attach to the anvil and the second tissue thickness compensator to attach to the staple cartridge. The retainer also may carry the staple cartridge with a tissue thickness compensator optionally disposed between the retainer and the staple cartridge. Closing the anvil causes the staple cartridge to attach to a channel of the surgical stapler and causes the first tissue thickness compensator to attach to the anvil.

FIGS. **90-93** show an embodiment of a retainer **19500**. The retainer **19500** includes a grip **19502** by which a surgeon, nurse, technician, or other person may manipulate the retainer **19500**. The grip **19502** may include a textured surface, such as raised portions **19503**, for example, which may provide a better gripping surface. In various embodiments, the retainer **19500** can include a surface **19504** on which a tissue thickness compensator may be mounted. The surface **19504** may include one or more projections **19506** wherein the projections **19506** may engage recesses in the tissue thickness compensator and align the tissue thickness compensator relative to the surface **19504** of the retainer **19500**. The recesses in the tissue thickness compensator may be slightly smaller than the projections **19506** such that, when engaged with the recesses, the projections **19506** can hold the tissue thickness compen-

sator to the surface **19504**. In various embodiments, the projections **19506** may pass through holes in the tissue thickness compensator and engage a slot, such as, for example, a cutting blade slot **19558** in anvil **19550** shown in FIG. **95**, thereby aligning the tissue thickness compensator with the retainer **19500** and also providing additional alignment of the retainer **19500** with the anvil **19550**. The tissue thickness compensator **19540** may include an adhesive and/or engagement features, described above, on a surface **19542** for attaching the tissue thickness compensator to an anvil **19550**.

As shown in FIG. **94**, in various embodiments, a staple cartridge **19530** may be attached to the retainer **19500**. The staple cartridge **19530** can be attached to the retainer **19500** by clips **19510** and **19512** extending from the retainer **19500**. Clips **19512** on the retainer **19500** can engage a slot **19534** in the staple cartridge **19530**. Clips **19510** of the retainer **19500** can surround the bottom **19532** of the staple cartridge **19532**. In various embodiments, a second tissue thickness compensator may be attached to the staple cartridge **19530**. In at least one embodiment, a second tissue thickness compensator may be attached to a staple deck **19536** of the staple cartridge **19530**.

As shown in FIGS. **95** and **96**, a retainer assembly **19590** comprising the retainer **19500**, a tissue thickness compensator **19540**, and a staple cartridge **19530**, can slide onto the anvil **19550** of a surgical device, such as a surgical stapler, in the direction of arrow L. The guide tabs **19508** on the retainer **19500** can surround edges **19552** of the anvil **19550** and position the retainer assembly **19590** relative to the anvil **19550**. After the retainer assembly **19590** is engaged on the anvil **19550**, as shown in FIGS. **97** and **98**, the anvil can be closed in the direction of arrow M. Closure of the anvil **19550** can position the staple cartridge **19530** in a channel **19560** of the surgical device. In at least one embodiment, closure of the anvil **19550** can cause the clips **19510** extending from the retainer **19500** to engage a ridge **19562** of the channel **19560** in order to securely position the staple cartridge **19530** in the channel **19560**. When the anvil **19550** is reopened in the direction of arrow N, referring now to FIGS. **99** and **100**, the tissue thickness compensator **19540** can remain attached to the anvil **19550** and separates from the retainer **19500**. The retainer **19500** then can be removed from the surgical instrument in the direction of arrow O (FIGS. **99** and **100**) leaving the staple cartridge **19530** in the channel **19560** of the surgical device and a tissue thickness compensator **19540** attached to the anvil **19550**.

FIGS. **101** and **102** show examples of two alternative embodiments of tissue thickness compensators **19570** and **19580**, respectively. FIG. **101** is a cross-sectional view of a tissue thickness compensator **19570** attached to a retainer **19501** wherein the tissue thickness compensator **19570** can include protrusions **19574** which can contact edges **19552** of the anvil **19550** and partially surround an exterior surface **19556** of the anvil **19550**. In various embodiments, the protrusions can grip the anvil **19550** and/or be attached to the anvil **19550** utilizing one or more adhesives. In order to release the tissue thickness compensator **19570** from the anvil **19550** after the compensator **19570** has been implanted against a patient's tissue, the protrusions **19574** can flex outwardly from the anvil **19550** thereby enabling the tissue thickness compensator **19570** to be pulled away from the anvil **19550**. FIG. **102** is a cross-sectional view of a tissue thickness compensator **19580** attached to the retainer **19501** shown in FIG. **101**. The tissue thickness compensator **19580** includes a sock **19584** that can surround the anvil **19550** to align the tissue thickness compensator **19580** with the anvil **19550** and/or to retain the tissue thickness compensator

**19580** on the anvil **19550**. In various embodiments, the sock **19584** can retain the tissue thickness compensator **19580** on the anvil **19550**. In order to detach the sock **19584** from the anvil **19550**, in various embodiments, the tissue thickness compensator **19580** can tear away from the sock **19584** at perforations **19586**, for example. Thus, the sock **19584** can remain on the anvil **19550** while the remainder of the tissue thickness compensator **19580** can remain stapled to the patient tissue.

In certain embodiments, a tissue thickness compensator, such as tissue thickness compensator **19570**, for example, can include an interior portion that comprises a biocompatible substance positioned therein. In various embodiments, the biocompatible substance can include an anti-inflammatory, a coagulant, and/or an antibiotic, for example. In various embodiments, a body, such as a wafer, for example can be inserted into the interior portion within the tissue thickness compensator. In at least one such embodiment, the wafer may be inserted through an open end of the tissue thickness compensator into a cavity defined therein. In certain embodiments, the wafer may be held within the cavity of the tissue thickness compensator by an interference fit. In certain embodiments, steps for assembling the wafer into the tissue thickness compensator can include a first step of heating the tissue thickness compensator such that the tissue thickness compensator expands. When the tissue thickness compensator expands, in various embodiments, the cavity defined therein can also expand. When the tissue thickness compensator is in an expanded state, according to a second step, the wafer may be inserted into the cavity. Then, as the tissue thickness compensator cools, according to a third step, the cavity can shrink onto the wafer and hold the wafer in place within the cavity.

FIGS. **103-115** illustrate an embodiment of a retainer comprising a separate insertion tool. The insertion tool can be used to insert an assembly into a surgical instrument, such as a surgical stapler, for example. The insertion tool can also press a staple cartridge and one or more tissue thickness compensators of the retainer assembly into position within the surgical instrument. Referring to FIGS. **103** and **104**, a retainer **19600** may include a first plate **19620** and a second plate **19622**. The first plate **19620** and the second plate **19622** may be connected by a hinge **19612**. The hinge **19612** can position the first plate **19620** at an angle relative to the second plate **19622** and can also enable the first plate **19620** to rotate relative to the second plate **19622** about the hinge **19612**.

In various embodiments, the first plate **19620** can include an outward-facing surface **19604** and an inward-facing surface **19606**. Likewise, the second plate **19622** may include an outward-facing surface **19610** and an inward-facing surface **19608**. In at least one embodiment, the inward-facing surface **19606** of the first plate **19620** may include a cam protrusion **19614**. Similarly, the inward-facing surface **19608** of the second plate **19622** may include a cam protrusion **19616**. Referring to FIGS. **110-115**, outward-facing surface **19604** of the first plate may include a tissue thickness compensator positioned thereon. Outward-facing surface **19601** of the second plate **19622** may also include a tissue thickness compensator positioned thereon. The tissue thickness compensators may be attached to the outer surfaces **19604** and **19610** using adhesives, engagement features, and/or other suitable attachment means, for example. In various embodiments, the retainer **19600** can include clips **19618** extending from the second plate **19622** which can be configured to engage a staple cartridge **19690**, as shown in FIGS. **110** and **112-115**.

Referring now to FIGS. **105-109**, an insertion tool **19630** can include a first end **19632** and a second end **19634**. The

first end **19632** can be large enough to be gripped by a surgeon, nurse, and/or technician, for example. In various embodiments, the second end **19634** defines a cavity **19640** wherein the cavity can include a cam **19648** positioned therein. A first side of the cam **19648** may include a first lobe **19642**, a second lobe **19644**, and a first anti-lobe **19646** positioned therebetween. A second side of the cam **19648** can include a third lobe **19643**, a fourth lobe **19645**, and a second anti-lobe **19647** positioned therebetween. In at least one such embodiment, the lobes and the anti-lobes can be arranged in a mirror-image manner. In other words, the first lobe **19642** may be arranged on the first side of the cam **19648** directly opposite the third lobe **19643** on the second side of the cam **19648**. Likewise, the second lobe **19644** may be arranged on the first side of the cam **19648** directly opposite the fourth lobe **19645** on the second side of the cam **19648**. Further, the first anti-lobe **19646** may be arranged on the first side of the cam **19648** directly opposite the second anti-lobe **19647** on the second side of the cam **19648**.

In use, the second end **19634** of the insertion tool **19630** is placed between the first plate **19620** and the second plate **19622** of the retainer **19600** such that the cam protrusion **19614** on the first plate **19620** is engaged with anti-lobe **19646** and cam protrusion **19616** on the second plate **19622** is engaged with anti-lobe **19647**, for example. As shown in FIGS. **112** and **113**, an insertion assembly **19700**, which includes the retainer **19600**, the insertion tool **19630**, one or more tissue thickness compensators, and staple cartridge **19690** can be inserted into a surgical instrument. The surgical instrument, such as a surgical stapler, may include a channel **19740**, which is configured to receive the staple cartridge **19690**, and an anvil **19720**. The insertion assembly **19700** can be inserted into the surgical instrument in the direction of arrow P (FIG. **113**) to lock the staple cartridge **19690** into the channel **19740**. In such a position, the cams **19614** and **19616** can be aligned with the anti-lobes **19646** and **19647**, respectively.

After the staple cartridge **19690** is locked into the channel **19740**, as shown in FIG. **114**, the insertion tool **19600** can continue to be moved in the direction of arrow Q relative to the surgical instrument. Further movement of the insertion tool **19600** in the direction of arrow Q can align the first lobe **19642** with the first cam protrusion **19614** and the third lobe **19643** with the second cam protrusion **19616**. Such an alignment can cause the retainer plates **19620** and **19622** to rotate away from each other about the hinge **19612** in the direction of arrow R (FIG. **114**). In such circumstances, the retainer plate **19620** and the tissue thickness compensator **19670** can move toward the anvil **19720** and the retainer plate **19622** can move toward and contact the anvil **19720**. In various embodiments, as a result of the above, the tissue thickness compensator **19670** can be seated on the anvil **19720**. After the tissue thickness compensator **19670** is attached to the anvil **19720**, the insertion tool **19630** may be retracted or moved in the direction of arrow S (shown in FIG. **115**). Movement of the insertion tool **19630** in the direction of arrow S can cause the cam protrusions **19614** and **19616** to disengage from the first lobe **19642** and the third lobe **19643**, respectively, and become re-aligned with the first anti-lobe **19646** and the second anti-lobe **19647**, respectively. In various embodiments, the second lobe **19644** and the fourth lobe **19645** can abut the cam protrusions **19614** and **19616**, respectively, and, in at least one embodiment, can prevent the insertion tool **19630** from completely separating from the retainer **19600**. With the cam protrusions **19614** and **19616** realigned with the anti-lobes **19646** and **19647**, the first plate **19620** can at least partially rotate toward the second plate **19622** about the hinge



**19612** and away from the anvil **19720**. The retainer **19600** can also be detached from the channel **19740**, in various embodiments, and then removed in the direction of arrow **S** leaving the tissue thickness compensator **19670** attached to the anvil **19720**, for example.

In the embodiments described herein, a retainer assembly can be utilized to install one or more tissue thickness compensators into an end effector of a surgical stapling instrument. In certain embodiments, a retainer assembly can install layers besides tissue thickness compensators into a surgical instrument. In at least one embodiment, the layers may include an absorbable material and/or a biocompatible material, for example.

Referring to FIG. **172**, an end effector **12** can be configured to receive an end effector insert **25002**. In various embodiments, the end effector **12** can comprise a lower jaw **25070** and an anvil **25060** that is configured to pivot relative to the lower jaw **25070**. In some embodiments, the end effector insert **25002** can comprise a staple cartridge **25000** that is pivotably connected to an anvil insert **25004**. The end effector **12** can be configured to receive the end effector insert **25002** such that the staple cartridge **25000** fits within a staple cartridge channel **25072** of the lower jaw **25070**, for example, and the anvil insert **25004** contacts the anvil **25060**, for example. In various embodiments, the lower jaw **25070** can comprise a plurality of securing members **25074** configured to secure the staple cartridge **25000** to the staple cartridge channel **25072**. In some embodiments, the anvil insert **25004** can comprise at least one retaining protrusion configured to engage at least one retaining groove in the anvil **25060**. The anvil insert **25004** can be configured to correspondingly pivot towards the staple cartridge **25000** when the anvil **25060** pivots towards the lower jaw **25070**, as described in greater detail herein.

Referring still to FIG. **172**, the end effector insert **25002** can further comprise a retainer **25010**. In various embodiments, the retainer **25010** can securely engage at least one of the staple cartridge **25000** and the anvil insert **25004**. In at least one embodiment, the retainer **25010** can comprise at least one securing clip **25012** that can clip, engage, snap, clamp, and/or hook the staple cartridge **25000**. As illustrated in FIG. **172**, the retainer **25010** can comprise two securing clips **25012** on each longitudinal side thereof, for example. In at least one such embodiment, the securing clips **25012** can be configured to clip onto a portion of the staple cartridge **25000**, for example. In various embodiments, a tissue thickness compensator can be held in position relative to the end effector insert **25002** by the retainer **25010**. For example, a tissue thickness compensator can be positioned between the retainer **25010** and the staple cartridge **25000**.

In various embodiments, when an operator is inserting the end effector insert **25002** into the end effector **12**, the retainer **25010** can provide a solid or substantially solid element for the operator to grasp. Furthermore, the retainer **25010** can prevent premature deformation of a tissue thickness compensator that is confined by the retainer **25010**, for example. In various embodiments, the retainer **25010** can be removed from the end effector **12** prior to utilizing the end effector **12** to cut and/or fasten tissue. In other embodiments, the retainer **25010** can remain positioned in the end effector **12**. For example, the retainer **25010** can be transected by the cutting element **25052** (FIG. **207**) as staples are fired from staples cavities **25002** (FIG. **207**) in the staple cartridge **25000**. In various embodiments, the retainer **25010** can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The retainer **25010** can further comprise a bioabsorbable polymer, such as, for

example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. In some embodiments, the retainer **25010** can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament.

Referring to FIG. **173**, an end effector **26012** can comprise an anvil **26060** and a lower jaw **26070**. In various embodiments, a tissue compensator **26020** can be releasably secured to the anvil **26060**, the lower jaw **26070**, and/or both the anvil **26060** and the lower jaw **26070**. For example, a first tissue compensator **26020** can be releasably secured to a staple cartridge **26000** in the lower jaw **26070** and a second tissue compensator **26022** can be releasably secured to the anvil **26060**. In various embodiments, the first and second tissue compensators **26020**, **26022** can be deformable and/or resilient, similar to at least one tissue thickness compensator described herein. For example, the first and second tissue compensators **26020**, **26022** can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The first and second tissue compensators **26020**, **26022** can further comprise a bioabsorbable polymer, such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. In some embodiments, the first and second tissue compensators **26020**, **26022** can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament.

In some embodiments, the tissue compensator **26020**, **26022** can comprise a firm or substantially firm tip **26024**, **26026**. For example, a first tip **26024** can be positioned at the distal end of the first tissue compensator **26020** and a second tip **26026** can be positioned at the distal end of the second tissue compensator **26022**. In various embodiments, the tips **26024**, **26026** may prevent or limit premature deformation of the tissue compensators **26020**, **26022**. For example, the tips **26024**, **26026** can protect the tissue compensators **26020**, **26022** when the tissue compensators **26020**, **26022** are moved through a trocar and/or maneuvered around a patient's tissue, for example. Similarly, referring to FIG. **174**, the end effector **12** can comprise a first tissue compensator **25020** releasably secured to the staple cartridge **25000** in the lower jaw **25070** and a second tissue compensator **25022** releasably secured to the anvil **25060**. In various embodiments, a tip **25026** can be positioned at the distal end of the second tissue compensator **25022**. The tip **25026** can be positioned adjacent to a deformable and/or resilient portion of the tissue compensator **25022**. In some embodiments, the tip **25026** can extend over and/or around a portion of the tissue compensator **25022**, such that the tip **25026** protects the distal end and an intermediate portion of the tissue compensator **25022**.

Referring to FIGS. **175-202**, a sleeve **27010** can be configured to engage the anvil **25060** of the end effector **12** of a surgical instrument, for example. In various embodiments, the sleeve **27010** can comprise a pronged portion **27040** (FIGS. **176-179**), a nose **27080** (FIGS. **186-189**) and a compensator **27120** (FIGS. **180-182**). In some embodiments, the sleeve **27010** can be configured to release a compensator **27020** when a translating firing bar **25052** (FIG. **196**) approaches the distal end of the end effector **12**. In various embodiments, the compensator **27020** can be deformable and/or resilient, similar to at least one tissue thickness compensator described herein. For example, the compensator **27020** can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The compensator **27020** can further comprise a bioabsorbable polymer, such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen,



and/or oxidized regenerated cellulose (ORC), for example. In some embodiments, the compensator 27020 can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament. Referring primarily to FIG. 175, the pronged portion 27040 can be positioned on and/or around an outer surface 25061 of the anvil 25060. In various embodiments, the nose 27080 of the sleeve 27010 can be positioned at and/or around a distal portion of the anvil 25060. In some embodiments, the compensator 27020 can be positioned on and/or around an inner surface of the anvil 25060.

Referring still to FIG. 175, the pronged portion 27040 can comprise at least one prong 27042a. In various embodiments, as illustrated in FIGS. 505-508, the pronged portion 27040 can comprise a first prong 27042a and a second prong 27042b. The prongs 27042a, 27042b can be symmetrical or substantially symmetrical, for example. In some embodiments, the first prong 27042a can be asymmetrical relative to the second prong 27042b. In various embodiments, the first and/or second prongs 27042a, 27042b can narrow at the distal end thereof. For example, each prong 27042a, 27042b can comprise a narrowed end 27048. Referring primarily to FIG. 178, the pronged portion 27040 can be contoured, for example. In various embodiments, referring again to FIG. 175, the contour of the pronged portion 27040 can match or substantially match a contour of the outer surface 25061 of the anvil 25060, for example. Referring primarily to FIGS. 178 and 179, the pronged portion 27040 can also comprise at least one catch 27044a extending from the first prong 27042a. In some embodiments, a first catch 27044a can be positioned on a first side of the pronged portion 27040 and a second catch 27044b can be positioned on a second side of the pronged portion 27040. In various embodiments, the catches 27044a, 27044b can be positioned at or near the proximal end of the pronged portion 27040, for example. In some embodiments, the catches 27044a, 27044b can be positioned at or near the distal end of the pronged portion 27040, such as along the first and/or second prongs 27042a, 27042b, for example. In various embodiments, the catches 27044a, 27044b can extend along a substantial length of the pronged portion 27040 and/or along a shorter length of the pronged portion 27040. In some embodiments, a plurality of catches 27044a, 27044b can be positioned along each longitudinal side of the pronged portion, for example. Referring primarily to FIG. 179, the first catch 27044a can comprise a first catch extension 27046a and/or the second catch 27044b can comprise a second catch extension 27046b. In various embodiments, the first catch extension 27046a can protrude from at least a portion of the catch 27044a and the second catch extension 27046b can protrude from at least a portion of the catch 27044b, for example. Further, the first catch extension 27046a and the second catch extension 27046b can each be configured to engage a gap 27128 (FIG. 181) in the compensator 27020, as described in greater detail herein.

Referring now to FIG. 201, the compensator 27020 for the sleeve 27010 can comprise a longitudinal protrusion 27024 and an edge 27026 on each longitudinal side of the compensator 27020. In various embodiments, the compensator 27020 can be positioned adjacent to an inner surface 25063 of the anvil 25060. Further, when the sleeve 27010 is positioned on the anvil 25060, the longitudinal protrusion 27024 can be substantially aligned with and/or positioned within a longitudinal slot 25062 in the anvil 25060. The edges 27026 of the compensator 27020 can at least partially wrap around the anvil 25060 towards the outer surface 25061 thereof. Referring primarily to FIGS. 180-181, a compensator 27120 for a sleeve 27110 can comprise a body 27122 having a longitudinal protrusion 27124 that extends along at least a portion of

the body 27122. The longitudinal protrusion 27124 can define a longitudinal path along the midline of the body 27122, for example. In various embodiments, the longitudinal protrusion 27124 can be received by the longitudinal slot 25062 (FIG. 201) in the anvil 25060 when the sleeve 27110 is positioned on the anvil 25060. Referring primarily to FIG. 182, the longitudinal protrusion 27124 can comprise a rounded projection. For example, the cross-section of the longitudinal protrusion 27124 can form an arc and/or partial ring. In other embodiments, the longitudinal protrusion 27124 can comprise an angular and/or stepped projection. The compensator 27120 can further comprise an edge 27126, which can be straight, bent, fluted, wavy, and/or zigzagged, for example. In various embodiments, the edge 27126 can comprise gaps 27128 that can be configured to receive the catch extensions 27046a, 27046b (FIG. 179) when the assembled sleeve 27110 is positioned on the anvil 25060. The catch extensions 27046a, 27046b can fit through the gap 27128 to engage the anvil 25060 such that the catch extensions 27046a, 27046b help to secure the sleeve 27110 to the anvil 25060, for example.

Referring primarily to FIGS. 183-185, a compensator 27220 for a sleeve 27210 can comprise a body 27222 comprising a longitudinal protrusion 27224 extending along at least a portion of the body 27222. In various embodiments, similar to the above, the longitudinal protrusion 27224 can be received by the longitudinal slot 25062 (FIG. 202) in the anvil 25060 when the sleeve 27210 is positioned on the anvil 25060. Referring primarily to FIG. 185, the longitudinal protrusion 27224 can comprise an angular projection such that the cross-section of the protrusion 27224 forms a substantially rectangular shape. The compensator 27220 can further comprise an edge 27226, which can be straight, bent, fluted, wavy, and/or zigzagged, for example. In various embodiments, the edge 27226 can comprise gaps 27228 that can be configured to receive the catch extensions 27046a, 27046b (FIG. 179) when the assembled sleeve 27210 is positioned on the anvil 25060. The catch extensions 27046a, 27046b can fit through the gaps 27228 and engage the anvil 25060 such that the catch extensions 27046a, 27046b help to secure the sleeve 27210 to the anvil 25060, for example. In various embodiments, the compensator 27220 can further comprise a plurality of ribs 27229 that laterally traverse the body 27222 of the compensator 27220. The ribs 27229 can support the body 27222 of the compensator 27220 when the sleeve 27210 is positioned on the anvil 25060 and/or when the compensator 27220 contacts tissue.

Referring to FIGS. 386-390, the nose 27080 of the sleeve 27010 can comprise an alignment ridge 27082 that can be substantially aligned with the longitudinal slot 25062 (FIG. 201) in the anvil 25060. When the alignment ridge 27082 is aligned with the longitudinal slot 25062 and when the sleeve 27010 is positioned on the anvil 25060, the nose 27082 can at least partially surround a distal portion of the pronged portion 27040 of the sleeve 27010. For example, the narrowed end 27048 of each prong 27042a, 27042b can be positioned within the nose 27080 when the sleeve 27010 is positioned on the anvil 25060. As described in greater detail herein, the nose 27080 can flex the prongs 27042a, 27042b closer together and/or downward when the pronged portion 27042 is engaged with the nose 27080. Furthermore, as illustrated in FIG. 190, when the narrowed ends 27048 of the pronged portion 27040 are positioned within the nose 27080, the catches 27044a, 27044b on the pronged portion 27040 can engage the edges 27026 of the compensator 27020, for example. As a result of such engagement, the compensator 27010 can be secured to the anvil 25060.

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Referring to FIGS. 191-195, when the nose 27080 is engaged with the pronged portion 27040 of the sleeve 27010, the compensator 27020 can be secured to the anvil 25060. The nose 27080 can remain engaged with the pronged portion 27040 as the firing bar 25050 translates along a portion of the longitudinal slot 25062 in the anvil 25060. Referring now to FIGS. 195-200, when the cutting element 25052 on the firing bar 25050, and/or any other suitable portion of the firing bar 25050, such as retaining flange 25054, for example, approaches the distal end of the anvil 25060, the firing bar 25050 can disengage the nose 27080 from the pronged portion 27040. The firing bar 25050 can, for example, contact the nose 27080 and push the nose 27080 off of the anvil 25060 such that the nose 27080 becomes disconnected from the pronged portion 27040 of the sleeve 27010. Referring now to FIG. 202, when the nose 27080 is disengaged with the pronged portion 27040, the first and second prongs 27042a, 27042b can be configured to flex away from the anvil 25060. For example, when the pronged portion 27070 is engaged with the nose 27080, the prongs 27042a, 27042b can be flexed closer together and/or downwards towards the anvil 25060 and held in such a position by the nose 27080. In various embodiments, the prongs 27042a, 27042b can be held under a spring load by the nose 27080 such that the prongs 27042a, 27042b seek to rebound to a neutral configuration once the nose 27080 is disengaged from the prongs 27042a, 27042b. In other embodiments, the prongs 27042a, 27042b can be sufficiently deformable such that the prongs 27042a, 27042b can be deformed or splayed outwardly by the firing bar 25050 once the nose 27080 is disengaged therefrom. When the prongs 27042a, 27042b move away from the anvil 25060, the catches 27044a, 27044b along a longitudinal side of each prong 27042a, 27042b can disengage the compensator 27020, which can allow the compensator 27020 to be released from the anvil 25060.

Referring to FIGS. 203-209, the end effector 12 of a surgical instrument, for example, can be configured to receive an end effector insert 28010. In various embodiments, the end effector insert 28010 can comprise a compensator body 28012 and at least one clip 28014a, 28014b. In various embodiments, the end effector insert 28010 can comprise a proximal clip 28014b at the proximal end of the compensator body 28012 and a distal clip 28014a at the distal end of the compensator body 28012, for example. Referring primarily to FIG. 206, the distal clip 28014a can be secured to the anvil 25060 of the end effector 12 at or near the distal end of the anvil 25060. For example, the distal clip 28014a can be substantially aligned with and/or partially positioned within the longitudinal slot 25062 of the anvil 25060. Referring primarily to FIG. 207, the proximal clip 28014b can be secured to a staple cartridge 25000 in the lower jaw 25070 of the end effector 12 (FIG. 208). The proximal clip 28014b can be secured to the staple cartridge 25000 at or near the proximal end of the staple cartridge 25000. For example, the proximal clip 28014b can be substantially aligned with and/or positioned within a longitudinal slot 25004 in the staple cartridge 25000.

Referring now to FIGS. 208 and 209, the end effector insert 28010 can be inserted into the end effector 12 of a surgical instrument. In various embodiments, at least a portion of the end effector insert 28010, such as the compensator body 28012, distal clips 28014a, and/or proximal clip 28014b, can be deformable and/or resilient, for example. When the end effector insert 28010 is inserted into the end effector 12, the distal and/or the proximal clips 28014a, 28014b can bend or flex. When the clips 28014a, 28014b are flexed, for example, the clips 28014a, 28014b can seek to return to their initial,

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undeformed configuration and can generate a corresponding springback or restoring force, for example. In various embodiments, when the end effector insert 28010 is positioned within the end effector 12, the end effector insert 28010 can apply a spring load to the end effector 12. In some embodiments, the end effector insert 28010 can be solid or substantially solid such that an operator can grasp the insert 28010 when the operator is inserting the end effector insert 28010 and staple cartridge 25000 into the end effector 12.

In some embodiments, the end effector insert 28010 can be removed from the end effector 12 prior to cutting and/or fastening operations of the end effector 12. In other embodiments, the end effector insert 28010 can remain positioned in the end effector 12 during cutting and/or firing operations. For example, the end effector insert 28010 can be transected by the cutting element 25052 as staples are fired from their staples cavities 25002 (FIG. 207) in the staple cartridge 25000. In various embodiments, the end effector insert 28010 can comprise a tissue thickness compensation material, similar to at least one of the tissue thickness compensators described herein. For example, the end effector insert 28010 can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The end effector insert 28010 can further comprise a bioabsorbable polymer, such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. In some embodiments, the end effector insert 28010 can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament.

Referring to FIGS. 210-215, a tissue thickness compensator 29020 can be positioned in the end effector 12 of a surgical instrument. The tissue thickness compensator 29020 can be substantially similar to at least one of the tissue thickness compensators described herein. For example, the tissue thickness compensator 29020 can be sufficiently deformable and resilient such that deformation of the tissue thickness compensator 29020 generates a springback or restoring force. In various embodiments, referring primarily to FIG. 211, a static charge can attract the tissue thickness compensator 29020 to the anvil 25060 of the end effector 12 such that the static charge secures the tissue thickness compensator 29020 to the anvil 25060. In various embodiments, the static charge can be neutralized such that the anvil 25060 releases the tissue thickness compensator 29020. Additionally or alternatively, referring now to FIG. 212, the tissue thickness compensator 29020 can be secured to the anvil 25060 by at least one suction element 29022. For example, a plurality of micro-suction elements 29022 on a surface of the tissue thickness compensator 29020 can releasably secure the tissue thickness compensator 29020 to the anvil 25060. Additionally or alternatively, referring to FIG. 213, hook and loop fasteners 29024 can secure the tissue thickness compensator 29020 to the anvil 25060. For example, a surface of the tissue thickness compensator 29020 can comprise a plurality of hook fasteners 29024a and a surface of the anvil 25060 can comprise a plurality of loop fasteners 29024b, for example. The hook fasteners 29024a can engage the loop fasteners 29024b such that the tissue thickness compensator 29020 is releasably secured to the anvil 25060.

Additionally or alternatively, referring now to FIG. 214, the tissue thickness compensator 29020 can be secured to the anvil 25060 by a band 29026. In some embodiments, the band 29026 can comprise an elastomeric polymer and/or can be tied or knotted around the anvil 25060. When the band 29026 is removed from the anvil 25060, the tissue thickness compensator 29020 can be released from the anvil 25060. To

facilitate removal of the band **29026**, it can be stretched and/or cut, for example. In various embodiments, a plurality of bands **29026** can secure the tissue thickness compensator **29020** to the anvil **25060**. Alternatively or additionally, referring now to FIG. **215**, the tissue thickness compensator **29020** can be secured to the anvil **25060** by a sock **29028** positioned at the distal end of the tissue thickness compensator **29020**. The sock **29028** can be configured to receive the distal end of the anvil **25060** therein, for example. In some embodiments, an alignment ledge **29029** on the tissue thickness compensator **29020** can be aligned with and/or positioned within the longitudinal slot **25062** in the anvil **25060**. For example, the alignment ledge **29029** can slide within the longitudinal slot **25062** as the tissue thickness compensator **29020** is positioned on and/or removed from the anvil **25060**.

Referring to FIGS. **216-218**, a tissue thickness compensator **30020** can be positioned on the anvil **25060** of the end effector **12** of the surgical instrument. In various embodiments, the tissue thickness compensator **30020** can comprise a body **30022** and a pocket **30024**. In at least one embodiment, a compensator material **30026** can be retained between the body **30022** and the pocket **30024**, for example. In some embodiments, the compensator material **30026** can comprise a bioabsorbable polymer, such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. Additionally or alternatively, the compensator material **30026** can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament. In various embodiments, the tissue thickness compensator **30020** can be deformable and/or resilient, similar to at least one tissue thickness compensator described herein. For example, the tissue thickness compensator **30020** can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The tissue thickness compensator **30020** can further comprise a bioabsorbable polymer, such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example.

Referring primarily to FIG. **217**, the body **30022** of the tissue thickness compensator **30020** can comprise an alignment element **30028** that can be received within the longitudinal slot **25062** of the anvil **25060** when the tissue thickness compensator **30020** is secured to the anvil **25060**. In some embodiments, the body **30022** can comprise a stepped thickness such that the geometry of the body **30022** substantially corresponds with the geometry of the anvil **25060**. Further, in various embodiments, the body **30022** can comprise longitudinal flanges **30029**. In at least one such embodiment, a longitudinal flange **30029** can extend along each longitudinal side of the body **30022** of the tissue thickness compensator **30020**, for example. In various embodiments, the longitudinal flanges **30029** can at least partially wrap around the anvil **25060** to secure the tissue thickness compensator **30020** to the anvil **25060**. Further, the longitudinal flanges **30029** can be sufficiently resilient such that the longitudinal flanges **30029** can flex to accommodate and/or engage the anvil **25060**, for example. In various embodiments, the longitudinal flanges **30029** can exert a clamping force on the anvil **25060** when the flanges **30029** engage the anvil **25060**. In some embodiments, the pocket **30024** can comprise an indentation **30025**. When the tissue thickness compensator **30020** is secured to the anvil **25060**, the indentation **30025** can be substantially aligned with the longitudinal slot **25062** in the anvil **25060**, for example. In various embodiments, the tissue thickness compensator **30020** can be thinner at the indenta-

tion **30025** such that the translating cutting element **25052** (FIG. **207**) severs the tissue thickness compensator **30020** where it is thinner.

Referring now to FIGS. **219** and **220**, a tissue thickness compensator **30120** can comprise a body **30122** that is configured to retain compensation material **30026** therein. In various embodiments, the tissue thickness compensator **30120** can comprise an alignment element **30128**, an indentation **30125**, and/or longitudinal flanges **30129**, similar to at least one of the embodiments described herein. In some embodiments, the tissue thickness compensator **30120** can also comprise a latch **30124** that can be moved between an open position and a closed position. When the latch **30124** is in the closed position, as illustrated in FIG. **219**, the compensation material **30026** can be enclosed within the body **30122** of the tissue thickness compensator **30120** and, when the latch **30124** is in the open position, as illustrated in FIG. **220**, the compensation material **30026** can escape from the body **30122**. Similar to at least one of the tissue thickness compensators described herein, the tissue thickness compensator **30120** can be deformable and/or resilient. For example, the tissue thickness compensator **30120** can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The tissue thickness compensator **30120** can further comprise a bioabsorbable polymer, such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. Owing to the resiliency of the tissue thickness compensator **30120**, at least a portion of the body **30122** can be flexed to move the latch **30124** between the open position and the closed position. In at least one embodiment, the body **30122** of the tissue thickness compensator **30120** can remain attached to the anvil when the anvil is removed from the surgical site. In at least one such embodiment, the body **30122** can be configured to tear away from any staples that may have captured the body **30122** therein.

Referring to FIG. **221**, a tissue thickness compensator **30220** can comprise a body **30222** and a pocket **30224**. The compensator material **30026** can be retained between the body **30222** and the pocket **30224**, for example. In various embodiments, the tissue thickness compensator **30220** can comprise an alignment element, an indentation, and/or longitudinal flanges **30229**, similar to at least one of the embodiments described herein. Further, at least one longitudinal flange **30229** can comprise a groove, or slot, **30228**, which can be configured to receive a tab **30225** extending from the pocket **30224** of the tissue thickness compensator **30220**. In such an embodiment, engagement of the groove **30228** and the tab **30225** can connect the body **30222** and the pocket **30224**. Further, in such an embodiment, the groove **30228** and tab **30225** connection can enclose and/or retain the compensation material **30026** within the tissue thickness compensator **30220**. Referring now to FIG. **222**, in various embodiments, a pocket **30324** of a tissue thickness compensator **30320** can comprise an anchor **30325** extending therefrom. Further, the tissue thickness compensator **30320** can comprise a body **30322** having an opening **30328**. In various embodiments, the anchor **30325** can extend from the pocket **30324** to engage the opening **30328** in the body **30322**. In such an arrangement, the pocket **30324** and the body **30222** can encase the compensation material **30026** therebetween. In at least one embodiment, the tissue thickness compensator **30320** can further comprise one or more flanges **30229** which can be mounted to the anvil in order to retain the body **30322** to the anvil.

Referring now to FIG. 223, a tissue thickness compensator 30420 can comprise a body 30422 and a pocket 30424. In various embodiments, the compensation material 30026 can be retained between the body 30422 and the pocket 30424 of the tissue thickness compensator 30420. In some embodiments, the body 30422 can comprise an orifice 30428 and the pocket 30424 can comprise an anchor 30425. The anchor 30425 can extend from the pocket 30424 and through the orifice 30428 of the body 30422, for example. In various embodiments, the anchor 30425 can engage the anvil 25060 when the tissue thickness compensator 30420 is secured to the anvil 25060, for example. The anchor 30525 can be sufficiently deformable and resilient such that the anchor 30425 flexes when it engages the anvil 25060. Further, in some embodiments, the flexed anchor 30425 can apply a clamping force to the anvil 25060 to secure or assist in securing the tissue thickness compensator 30420 to the anvil 25060. In other embodiments, an anchor may not extend completely through an orifice in the compensator body. Referring to FIG. 224, an anchor 30525 on a pocket 30524 of a tissue thickness compensator 30520 can engage an orifice 30528 in a body 30522 of the tissue thickness compensator 30520. In various embodiments, the anchor 30525 can engage the orifice 30528 to secure the pocket 30524 to the body 30522. For example, the orifice 30528 can comprise a necked portion that extends to a socket. The anchor 30525 can comprise securing edge, which can pass through the necked portion and engage the socket to secure the anchor 30525 within the orifice 30528. Similar to at least one of the embodiments described herein, the tissue thickness compensator 30520 can also comprise an alignment element, an indentation, and/or longitudinal flanges 30529, for example.

Referring to FIGS. 225-227, a tissue thickness compensator 31020 can be configured to engage an anvil 31060 of an end effector 31012 of a surgical instrument. In various embodiments, the tissue thickness compensator 31020 can comprise an outer film 31022, an inner film 31024 and a compensation material 31026 positioned therebetween. In various embodiments, the tissue thickness compensator 31020 can be deformable and/or resilient, similar to at least one of the tissue thickness compensators described herein. For example, the compensation material 31026 can comprise a polymeric composition, such as a bioabsorbable, biocompatible elastomeric polymer, for example. The tissue thickness compensator 31020 can further comprise a bioabsorbable polymer such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. In some embodiments, the tissue thickness compensator 31020 can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament. In various embodiments, the compensation material 31026 of the tissue thickness compensator 31020 can comprise a therapeutic agent.

The inner film 31024 can be positioned adjacent to staple forming pockets 31066 in the anvil 31060, for example. Referring primarily to FIG. 225, the inner film 31024 can comprise a stepped geometry such that the geometry of the inner film 31024 substantially corresponds to the geometry of the anvil 31060. The inner film 31024 can further comprise an alignment ridge 31028, which can be substantially aligned with and/or parallel to a longitudinal slot 31062 in the anvil 31060, for example. As described in greater detail herein, the inner film 31024 can comprise an inner flange 31025 extending from each longitudinal side of the inner film 31024 and terminating in a catch 31027. The outer film 31022 can comprise a body 31021 and at least one outer flange 31023, for

example. In various embodiments, an outer flange 31023 can extend from each longitudinal side of the body 31021, for example. In various embodiments, the outer flange 31023 can be secured to the inner flange 31025 such that the compensation material 31026 is retained between the outer film 31022 and the inner film 31024.

Referring primarily to FIG. 227, the anvil 31060 can comprise an outer surface 31061 and at least one groove 31064 along at least a portion of the outer surface 31061. In various embodiments, a catch 31027 on the inner flange 31025 of the inner film 31024 can be positioned within a groove 31064. Referring to FIG. 226, for example, the tissue thickness compensator 31020 can be slid around the anvil 31060. In various embodiments, the grooves 31064 on the anvil 31060 can extend to the distal end of the anvil 31060. In such embodiments, the catches 31027 of the tissue thickness compensator 31020 can slide into the grooves 31064 and along a length of the tissue thickness compensator 31020.

In various embodiments, referring now to FIGS. 228 and 229, a tissue thickness compensator 31120 can comprise a compensation material 31026 and at least one connector 31124. Each connector 31124 can extend around the compensation material 31026 and can terminate in a catch 31127 on opposite ends thereof. In various embodiments, the catches 31127 can be positioned within the grooves 31064 of the anvil 31060 to fasten the tissue thickness compensator 31120 to the anvil 31060. In various embodiments, the grooves 31164 on the anvil 31060 can extend to the distal end of the anvil 31060. In such embodiments, the catches 31127 of the connectors 31124 can slide into the grooves 31064. In other embodiments, the connectors 31224 can be resilient such that they can flex and snap around the anvil 31060. In use, the connectors 31224 can hold the compensation material 31026 in place until the compensation material 31026 detaches from the anvil 31060. In certain circumstances, the connectors 31224 can remain attached to the anvil 31060 and can be removed from the surgical site with the anvil. In certain other circumstances, the connectors 31224 can detach from the anvil 31060 and can be implanted with the compensation material 31026.

Referring to FIGS. 230-236, a tissue thickness compensator 32020 can comprise a body portion 32022, at least one longitudinal flange 32024, and at least one pocket 32026. In various embodiments, the tissue thickness compensator 31020 can be deformable and/or resilient, similar to at least one of the tissue thickness compensators described herein. For example, the compensation material 31026 can comprise a polymeric composition such as a bioabsorbable, biocompatible elastomeric polymer, for example. The tissue thickness compensator 31020 can further comprise a bioabsorbable polymer such as, for example, lyophilized polysaccharide, glycoprotein, elastin, proteoglycan, gelatin, collagen, and/or oxidized regenerated cellulose (ORC), for example. In various embodiments, the longitudinal flange 32024 can extend along each longitudinal side of the body portion 32022. Referring primarily to FIG. 233, the longitudinal flanges 32024 of the tissue thickness compensator 32020 can be configured to engage the anvil 25060. For example, the tissue thickness compensator 32020 can slide onto the anvil 25060 and the longitudinal flanges 32024 and can at least partially wrap around a portion of the anvil 25060. In such embodiments, the flanges 32024 can secure the tissue thickness compensator 32020 to the anvil 25060, for example. In various embodiments, when the tissue thickness compensator 32020 is secured to the anvil, the body portion

**32022** of the tissue thickness compensator **32020** can overlap staple forming pockets **25066** on the inner surface of the anvil **25060**.

Further to the above, in various embodiments, a plurality of pockets **32026** can laterally traverse the body portion **32022**. Referring primarily to FIG. **234**, the plurality of pockets **32026** can comprise at least one therapeutic agent such as a pharmaceutically active agent or medicament. In various embodiments, a plurality of first pockets **32026a** can comprise a first therapeutic agent or combination thereof and a plurality of second pockets **32026b** can comprise a second therapeutic agent or combination thereof. The first pockets **32026a** and the second pockets **32026b** can be alternately positioned along the body portion **32022**, for example. Further, in various embodiments, when the first therapeutic agent is released from the first pocket **32026a** and the second therapeutic agent is released from the second pocket **32026b**, the first and second therapeutic agents can be configured to react with each other. Referring to FIG. **236**, the pockets **32026** can release the therapeutic agent(s) retained therein when the cutting element **25052** on the firing bar **25050** translates along the longitudinal slot **25062** in the anvil **25060**, for example.

In various embodiments, referring now to FIG. **237**, an end effector of a surgical stapling instrument can comprise an anvil **32560** and a staple cartridge **32500** comprising a tissue thickness compensator **32520**. Similar to the above, the staple cartridge **32500** can comprise a plurality of staples **32530** at least partially contained therein which can be ejected therefrom to capture the tissue thickness compensator **32520** therein. Also similar to the above, the staples **32530** can penetrate the tissue thickness compensator **32520** and contact staple forming pockets **32562** defined in the anvil **32560**. In certain embodiments, referring now to FIG. **239**, the anvil **32560** can further comprise a layer **32570** attached thereto which can be configured to retain a tissue thickness compensator **32580** to the anvil **32560**. In at least one such embodiment, the layer **32570** can comprise a chargeable layer which can be configured to hold and/or generate an electrostatic charge and attract the tissue thickness compensator **32580** thereto. More specifically, in various embodiments, Van der Waals molecular forces, whether actively or passively actuated, for example, can hold the tissue thickness compensator **32580** to the layer **32570**. In certain embodiments, the chargeable layer **32570** can be in electrical communication with a handle of the surgical stapling instrument which can comprise a control configured to selectively couple the chargeable layer **32570** with a power source and, as a result, allow an electrostatic charge to be selectively generated within the chargeable layer **32570**. In at least one such embodiment, the chargeable layer **32570** can comprise conductive electrodes embedded within a polymer, for example. In any event, the statically-charged layer **32570** can attract oppositely-charged particles in the tissue thickness compensator **32580** and hold the tissue thickness compensator **32580** to the anvil. In certain embodiments, referring now to FIG. **238**, the chargeable layer **32570** can comprise a grid, or lattice, of conductors **32571** which are in electrical communication with one another. In at least one such embodiment, the conductors can be positioned and arranged such that they surround the staple forming pockets **32562** defined in the anvil **32560**. In such embodiments, staples **32530** can be ejected from the staple cartridge **32500** and then deformed by the anvil **32560** without capturing the conductors **32571** therein. In various circumstances, the chargeable layer **32570** can be uncoupled from the power source after the staples **32530** have been engaged with the tissue thickness compensator **32580** such that the electrostatic charge in the layer **32570** can dissipate. In certain other

circumstances, the chargeable layer **32570** can be uncoupled from the power source prior to the staples **32530** being fired. In any event, as the electrostatic charge dissipates, the anvil **32560** can be re-opened and the layer **32570** can be moved away from the tissue thickness compensator **32580**. In some embodiments, the electrostatic charge may need to dissipate completely before the layer **32570** can be detached from the tissue thickness compensator **32580** while, in other embodiments, the layer **32570** can be detached from the tissue thickness compensator **32580** before the electrostatic charge in the layer **32570** has completely dissipated. In certain embodiments, as a result of the above, the tissue thickness compensator **32580** can be attached to the anvil **32560** without the use of a chemical adhesive.

In various embodiments, further to the above, the layer **32570** can also provide feedback capability to the handle of the surgical stapling instrument. In at least one such embodiment, the layer **32570** can be pressure sensitive and can be configured to detect the clamping pressure being applied thereto by the anvil **32560**, for example.

In various embodiments, further to the above, a tissue thickness compensator can be comprised of a biocompatible material. The biocompatible material, such as, a foam, may comprise tackifiers, surfactants, fillers, cross-linkers, pigments, dyes, antioxidants and other stabilizers and/or combinations thereof to provide desired properties to the material. In certain embodiments, a biocompatible foam may comprise a surfactant. The surfactant may be applied to the surface of the material and/or dispersed within the material. Without wishing to be bound to any particular theory, the surfactant applied to the biocompatible material may reduce the surface tension of the fluids contacting the material. For example, the surfactant may reduce the surface tension of water contacting the material to accelerate the penetration of water into the material. In various embodiments, the water may act as a catalyst. The surfactant may increase the hydrophilicity of the material.

In various embodiments, the surfactant may comprise an anionic surfactant, a cationic surfactant, and/or a non-ionic surfactant. Examples surfactants include, but are not limited to polyacrylic acid, methalose, methyl cellulose, ethyl cellulose, propyl cellulose, hydroxy ethyl cellulose, carboxy methyl cellulose, polyoxyethylene cetyl ether, polyoxyethylene lauryl ether, polyoxyethylene octyl ether, polyoxyethylene octylphenyl ether, polyoxyethylene oleyl ether, polyoxyethylene sorbitan monolaurate, polyoxyethylene stearyl ether, polyoxyethylene nonylphenyl ether, dialkylphenoxy poly(ethyleneoxy) ethanol, and polyoxamers, and combinations thereof. In at least one embodiment, the surfactant may comprise a copolymer of polyethylene glycol and polypropylene glycol. In at least one embodiment, the surfactant may comprise a phospholipid surfactant. The phospholipid surfactant may provide antibacterial stabilizing properties and/or disperse other materials in the biocompatible material. In various embodiments, the tissue thickness compensator may comprise at least one medicament. The tissue thickness compensator may comprise one or more of the natural materials, non-synthetic materials, and/or synthetic materials described herein. In certain embodiments, the tissue thickness compensator may comprise a biocompatible foam comprising gelatin, collagen, hyaluronic acid, oxidized regenerated cellulose, polyglycolic acid, polycaprolactone, polylactic acid, polydioxanone, polyhydroxyalkanoate, poliglecaprone, and combinations thereof. In certain embodiments, the tissue thickness compensator may comprise a film comprising the at least one medicament. In certain embodiments, the tissue thickness compensator may comprise a biodegradable film com-

prising the at least one medicament. In certain embodiments, the medicament may comprise a liquid, gel, and/or powder. In various embodiments, the medicaments may comprise anti-cancer agents, such as, for example, cisplatin, mitomycin, and/or adriamycin.

In various embodiments, the tissue thickness compensator may comprise a biodegradable material to provide controlled elution or release of the at least one medicament as the biodegradable material degrades. In various embodiments, the biodegradable material may degrade may decompose, or loses structural integrity, when the biodegradable material contacts an activator, such as, for example an activator fluid. In various embodiments, the activator fluid may comprise saline or any other electrolyte solution, for example. The biodegradable material may contact the activator fluid by conventional techniques, including, but not limited to spraying, dipping, and/or brushing. In use, for example, a surgeon may dip an end effector and/or a staple cartridge comprising the tissue thickness compensator comprising the at least one medicament into an activator fluid comprising a salt solution, such as sodium chloride, calcium chloride, and/or potassium chloride. The tissue thickness compensator may release the medicament as the tissue thickness compensator degrades. In certain embodiments, the elution or release of the medicament from the tissue thickness compensator may be characterized by a rapid initial elution or release rate and a slower sustained elution or release rate.

In various embodiments, a tissue thickness compensator, for example, can be comprised of a biocompatible material which may comprise an oxidizing agent. In various embodiments, the oxidizing agent may be an organic peroxide and/or an inorganic peroxide. Examples of oxidizing agents may include, but are not limited to, hydrogen peroxide, urea peroxide, calcium peroxide, and magnesium peroxide, and sodium percarbonate. In various embodiments, the oxidizing agent may comprise peroxygen-based oxidizing agents and hypochlorite-based oxidizing agents, such as, for example, hydrogen peroxide, hypochlorous acid, hypochlorites, hypochlorides, and percarbonates. In various embodiments, the oxidizing agent may comprise alkali metal chlorites, hypochlorites and perborates, such as, for example, sodium chlorite, sodium hypochlorite and sodium perborate. In certain embodiments, the oxidizing agent may comprise vanadate. In certain embodiments, the oxidizing agent may comprise ascorbic acid. In certain embodiments, the oxidizing agent may comprise an active oxygen generator. In various embodiments, a tissue scaffold may comprise the biocompatible material comprising an oxidizing agent.

In various embodiments, the biocompatible material may comprise a liquid, gel, and/or powder. In certain embodiments, the oxidizing agent may comprise microparticles and/or nanoparticles, for example. For example, the oxidizing agent may be milled into microparticles and/or nanoparticles. In certain embodiments, the oxidizing agent may be incorporated into the biocompatible material by suspending the oxidizing agent in a polymer solution. In certain embodiments, the oxidizing agent may be incorporated into the biocompatible material during the lyophilization process. After lyophilization, the oxidizing agent may be attached to the cell walls of the biocompatible material to interact with the tissue upon contact. In various embodiments, the oxidizing agent may not be chemically bonded to the biocompatible material. In at least one embodiment, a percarbonate dry power may be embedded within a biocompatible foam to provide a prolonged biological effect by the slow release of oxygen. In at least one embodiment, a percarbonate dry power may be embedded within a polymeric fiber in a non-woven structure

to provide a prolonged biological effect by the slow release of oxygen. In various embodiments, the biocompatible material may comprise an oxidizing agent and a medicament, such as, for example, doxycycline and ascorbic acid.

In various embodiments, the biocompatible material may comprise a rapid release oxidizing agent and/or a slower sustained release oxidizing agent. In certain embodiments, the elution or release of the oxidizing agent from the biocompatible material may be characterized by a rapid initial elution or release rate and a slower sustained elution or release rate. In various embodiments, the oxidizing agent may generate oxygen when the oxidizing agent contacts bodily fluid, such as, for example, water. Examples of bodily fluids may include, but are not limited to, blood, plasma, peritoneal fluid, cerebral spinal fluid, urine, lymph fluid, synovial fluid, vitreous fluid, saliva, gastrointestinal luminal contents, and/or bile. Without wishing to be bound to any particular theory, the oxidizing agent may reduce cell death, enhance tissue viability and/or maintain the mechanical strength of the tissue to tissue that may be damaged during cutting and/or stapling.

In various embodiments, the biocompatible material may comprise at least one microparticle and/or nanoparticle. The biocompatible material may comprise one or more of the natural materials, non-synthetic materials, and synthetic materials described herein. In various embodiments, the biocompatible material may comprise particles having a mean diameter of about 10 nm to about 100 nm and/or about 10  $\mu$ m to about 100  $\mu$ m, such as, for example, 45-50 nm and/or 45-50  $\mu$ m. In various embodiments, the biocompatible material may comprise biocompatible foam comprising at least one microparticle and/or nanoparticle embedded therein. The microparticle and/or nanoparticle may not be chemically bonded to the biocompatible material. The microparticle and/or nanoparticle may provide controlled release of the medicament. In certain embodiments, the microparticle and/or nanoparticle may comprise at least one medicament. In certain embodiments, the microparticle and/or nanoparticle may comprise a hemostatic agent, an anti-microbial agent, and/or an oxidizing agent, for example. In certain embodiments, the tissue thickness compensator may comprise a biocompatible foam comprising an hemostatic agent comprising oxidized regenerated cellulose, an anti-microbial agent comprising doxycycline and/or Gentamicin, and/or an oxidizing agent comprising a percarbant. In various embodiments, the microparticle and/or nanoparticle may provide controlled release of the medicament up to three days, for example.

In various embodiments, the microparticle and/or nanoparticle may be embedded in the biocompatible material during a manufacturing process. For example, a biocompatible polymer, such as, for example, a PGA/PCL, may contact a solvent, such as, for example, dioxane to form a mixture. The biocompatible polymer may be ground to form particles. Dry particles, with or without ORC particles, may be contacted with the mixture to form a suspension. The suspension may be lyophilized to form a biocompatible foam comprising PGA/PCL having dry particles and/or ORC particles embedded therein.

In various embodiments, the tissue thickness compensators or layers disclosed herein can be comprised of an absorbable polymer, for example. In certain embodiments, a tissue thickness compensator can be comprised of foam, film, fibrous woven, fibrous non-woven PGA, PGA/PCL (Poly(glycolic acid-co-caprolactone)), PLA/PCL (Poly(lactic acid-co-polycaprolactone)), PLLA/PCL, PGA/TMC (Poly(glycolic acid-co-trimethylene carbonate)), PDS, PEPBO or other absorbable polyurethane, polyester, polycarbonate, Polyorthoesters, Polyanhydrides, Polyesteramides, and/or

Polyoxaesters, for example. In various embodiments, a tissue thickness compensator can be comprised of PGA/PLA (Poly (glycolic acid-co-lactic acid)) and/or PDS/PLA (Poly(p-dioxanone-co-lactic acid)), for example. In various embodiments, a tissue thickness compensator can be comprised of an organic material, for example. In certain embodiments, a tissue thickness compensator can be comprised of Carboxymethyl Cellulose, Sodium Alginate, Cross-linked Hyaluronic Acid, and/or Oxidized regenerated cellulose, for example. In various embodiments, a tissue thickness compensator can comprise a durometer in the 3-7 Shore A (30-50 Shore 00) ranges with a maximum stiffness of 15 Shore A (65 Shore 00), for example. In certain embodiments, a tissue thickness compensator can undergo 40% compression under 3 lbf load, 60% compression under 6 lbf load, and/or 80% compression under 20 lbf load, for example. In certain embodiments, one or more gasses, such as air, nitrogen, carbon dioxide, and/or oxygen, for example, can be bubbled through and/or contained within the tissue thickness compensator. In at least one embodiment, a tissue thickness compensator can comprise beads therein which comprise between approximately 50% and approximately 75% of the material stiffness comprising the tissue thickness compensator.

In various embodiments, a tissue thickness compensator can comprise hyaluronic acid, nutrients, fibrin, thrombin, platelet rich plasma, Sulfasalazine (Azulfidine®-5ASA+Sulfapyridine diazo bond)-prodrug-colonic bacterial (Azoreductase), Mesalamine (5ASA with different prodrug configurations for delayed release), Asacol® (5ASA+Eudragit-S coated-pH>7 (coating dissolution)), Pentasa® (5ASA+ethylcellulose coated-time/pH dependent slow release), Mesasal® (5ASA+Eudragit-L coated-pH>6), Olsalazine (5ASA+5ASA-colonic bacterial (Azoreductase)), Balsalazide (5ASA+4-Aminobenzoyl-B-alanine)-colonic bacterial (Azoreductase), Granulated mesalamine, Lialda (delay and SR formulation of mesalamine), HMPL-004 (herbal mixture that may inhibit TNF-alpha, interleukin-1 beta, and nuclear-kappa B activation), CCX282-B (oral chemokine receptor antagonist that interferes with trafficking of T lymphocytes into the intestinal mucosa), Rifaximin (nonabsorbable broad-spectrum antibiotic), Infliximab, murine chymieric (monoclonal antibody directed against TNF-alpha-approved for reducing signs/symptoms and maintaining clinical remission in adult/pediatric patients with moderate/severe luminal and fistulizing Crohn's disease who have had inadequate response to conventional therapy), Adalimumab, Total Human IgG1 (anti-TNF-alpha monoclonal antibody—approved for reducing signs/symptoms of Crohn's disease, and for the induction and maintenance of clinical remission in adult patients with moderate/severe active Crohn's disease with inadequate response to conventional therapies, or who become intolerant to Infliximab), Certolizumab pegol, humanized anti-TNF FAB' (monoclonal antibody fragment linked to polyethylene glycol—approved for reducing signs/symptoms of Crohn's disease and for the induction and maintenance of response in adult patients w/moderate/severe disease with inadequate response to conventional therapies), Natalizumab, First non-TNF-alpha inhibitor (biologic compound approved for Crohn's disease), Humanized monoclonal IgG4 antibody (directed against alpha-4 integrin—FDA approved for inducing and maintaining clinical response and remission in patients with moderate/severe disease with evidence of inflammation and who have had inadequate response to or are unable to tolerate conventional Crohn's therapies and inhibitors of TNF-alpha), concomitant Immunomodulators potentially given with Infliximab, Azathioprine 6-Mercaptopurine (purine synthesis inhibitor-pro-

drug), Methotrexate (binds dihydrofolate reductase (DHFR) enzyme that participates in tetrahydrofolate synthesis, inhibits all purine synthesis), Allopurinol and Thioprine therapy, PPI, H2 for acid suppression to protect the healing line, C-Diff-Flagyl, Vancomycin (fecal translocation treatment; probiotics; repopulation of normal endoluminal flora), and/or Rifaximin (treatment of bacterial overgrowth (notably hepatic encephalopathy); not absorbed in GI tract with action on intraluminal bacteria), for example.

As described herein, a tissue thickness compensator can compensate for variations in the thickness of tissue that is captured within the staples ejected from a staple cartridge and/or contained within a staple line, for example. Stated another way, certain staples within a staple line can capture thick portions of the tissue while other staples within the staple line can capture thin portions of the tissue. In such circumstances, the tissue thickness compensator can assume different heights or thicknesses within the staples and apply a compressive force to the tissue captured within the staples regardless of whether the captured tissue is thick or thin. In various embodiments, a tissue thickness compensator can compensate for variations in the hardness of the tissue. For instance, certain staples within a staple line can capture highly compressible portions of the tissue while other staples within the staple line can capture portions of the tissue which are less compressible. In such circumstances, the tissue thickness compensator can be configured to assume a smaller height within the staples that have captured tissue having a lower compressibility, or higher hardness, and, correspondingly, a larger height within the staples that have captured tissue having a higher compressibility, or lower hardness, for example. In any event, a tissue thickness compensator, regardless of whether it compensates for variations in tissue thickness and/or variations in tissue hardness, for example, can be referred to as a 'tissue compensator' and/or as a 'compensator', for example.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.



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Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

While this invention has been described as having exemplary designs, the present invention may be further modified within the spirit and scope of the disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains.

What is claimed is:

1. A compensator attachable to an anvil of a fastening instrument, wherein the anvil includes a forming surface, and wherein said compensator comprises:

a compressible compensator body, comprising:

a plurality of first packets;

a plurality of second packets, wherein each said second packet is positioned intermediate two or more said first packets;

a first medicament enclosed within each said first packet until each said first packet is opened;

a second medicament enclosed within each said second packet until each said second packet is opened, wherein said first medicament is different than said second medicament; and

an attachment portion configured to be attached to the anvil.

2. The compensator of claim 1, wherein said first medicament comprises a first powder and said second medicament comprises a second powder.

3. The compensator of claim 1, wherein said first medicament comprises alginate and said second medicament comprises calcium.

4. The compensator of claim 1, wherein said compensator body comprises a longitudinal axis, and wherein said first packets and said second packets are arranged in an alternating arrangement along said longitudinal axis.

5. The compensator of claim 1, wherein said first packets and said second packets are arranged in an alternating arrangement.

6. The compensator of claim 1, wherein said first medicament can comprise non-woven oxidized regenerated cellulose.

7. A stapling assembly for use with a stapler, said stapling assembly comprising:

an anvil, comprising:

a plurality of forming surfaces; and

a slot configured to receive a cutting member therein;

a compensator attached to said anvil, wherein said compensator comprises a plurality of first packets aligned with said slot and a plurality of second packets aligned with said slot, and wherein said first packets and said second packets are configured to be incised by the cutting member;

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a first medicament enclosed within each said first packet until each said first packet is incised by the cutting member; and

a second medicament enclosed within each said second packet until each said second packet is incised by the cutting member, wherein said first medicament is different than said second medicament.

8. The stapling assembly of claim 7, wherein said slot defines a path for the cutting member, and wherein said first packets and said second packets extend in a direction which is transverse to said path.

9. The stapling assembly of claim 7, wherein said compensator comprises an attachment portion configured to fit within said slot, and wherein said attachment portion is configured to be incised by the cutting member.

10. The stapling assembly of claim 7, wherein said first medicament comprises a first powder and said second medicament comprises a second powder.

11. The stapling assembly of claim 7, wherein said first medicament comprises alginate and said second medicament comprises calcium.

12. The stapling assembly of claim 7, wherein said first packets and said second packets are arranged in an alternating arrangement along said slot.

13. A stapling assembly for use with a stapler, said stapling assembly comprising:

an anvil, comprising:

a plurality of forming surfaces; and

a longitudinal slot;

a cutting member configured to be moved within said slot;

a compensator attached to said anvil, wherein said compensator comprises a plurality of first lateral cavities extending laterally relative to said slot and a plurality of second lateral cavities extending laterally relative to said slot, and wherein said cutting member is configured to incise said first lateral cavities and said second lateral cavities;

a first medicament enclosed within each said first lateral cavity, wherein said first medicament is configured to be released from each said first lateral cavity when said first lateral cavity is incised by said cutting member; and

a second medicament enclosed within each said second lateral cavity, wherein said first medicament is different than said second medicament, and wherein said second medicament is configured to be released from each said second lateral cavity when said second lateral cavity is incised by said cutting member.

14. The stapling assembly of claim 13, wherein said compensator comprises an attachment portion configured to fit within said longitudinal slot, and wherein said cutting member is configured to incise said attachment portion.

15. The stapling assembly of claim 13, wherein said first medicament comprises a first powder and said second medicament comprises a second powder.

16. The stapling assembly of claim 13, wherein said first medicament comprises alginate and said second medicament comprises calcium.

17. The stapling assembly of claim 13, wherein said first lateral cavities and said second lateral cavities are arranged in an alternating arrangement along said longitudinal slot.

18. The stapling assembly of claim 13, wherein said longitudinal slot defines a longitudinal axis, and wherein said first lateral cavities and said second lateral cavities each define a lateral axis perpendicular to said longitudinal axis.



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**19.** A staple cartridge assembly for use with a surgical stapler, said staple cartridge assembly comprising:  
a cartridge body;  
a plurality of staple cavities;  
a plurality of staples removably stored within said staple 5 cavities; and  
a layer, comprising:  
a plurality of first packets;  
a plurality of second packets, wherein each said second packet is positioned intermediate two or more said 10 first packets;  
a first medicament enclosed within each said first packet until each said first packet is opened; and  
a second medicament enclosed within each said second packet until each said second packet is opened, 15 wherein said first medicament is different than said second medicament.

**20.** The staple cartridge assembly of claim **19**, further comprising an anvil.

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